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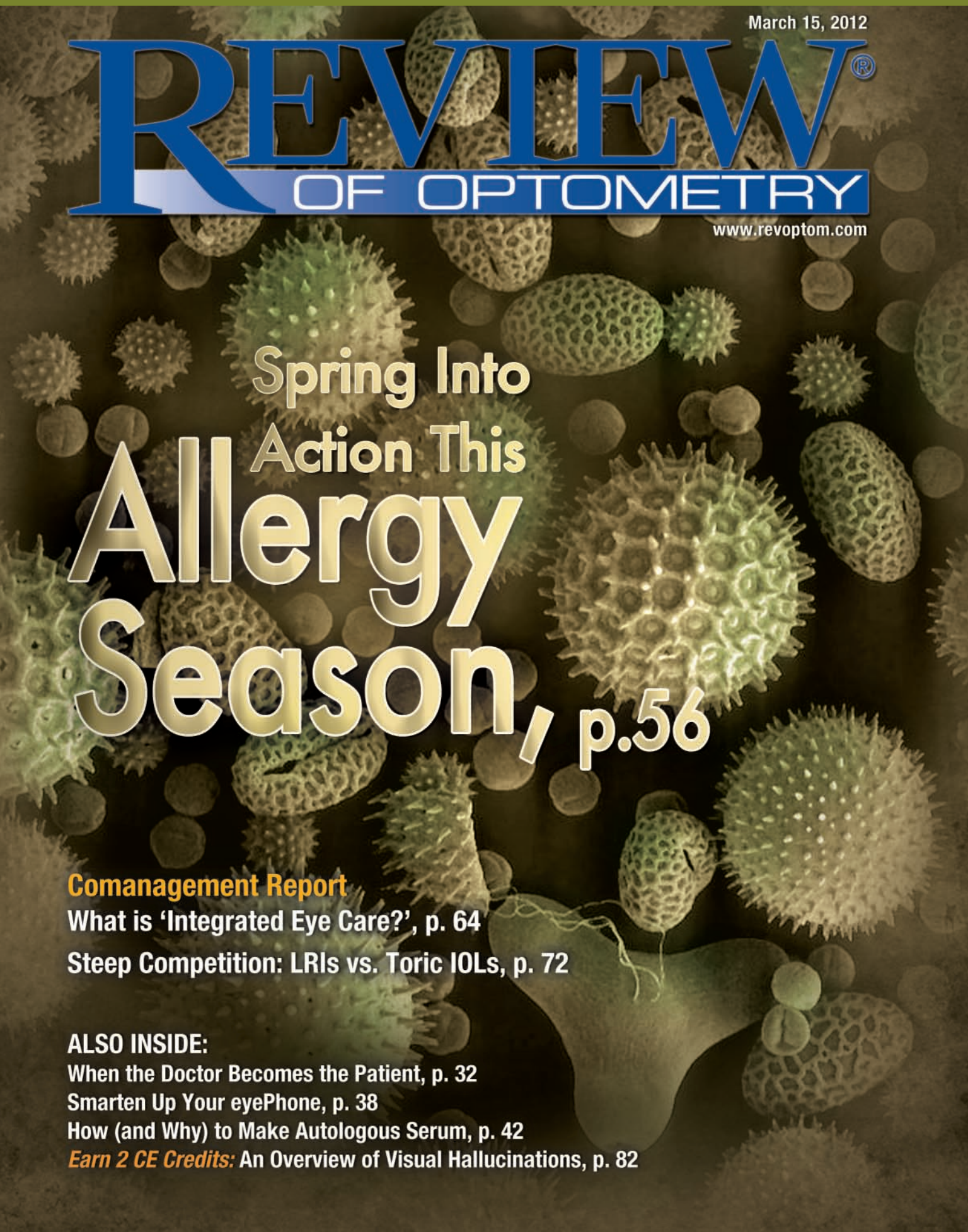

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IN THE NEWS

Southern College of Optometry announced a **$9.4 million building project** that will provide its students with new classroom facilities and state-of-the-art instructional space on campus. The **new building** will be located behind the college's 11-story tower. SCO breaks ground May 11. The school expects the building to be ready for use in **August 2013**. When completed, the building project will add 23,016 sq. ft. to the campus.

Arthur Dorman, O.D., who served 38 years in the Maryland State House as a delegate and senator before retiring in 2003, died Feb. 17 at his home in Charlottesville, Va. He was 85. Dr. Dorman ran a private optometry practice in Langley Park before retiring in the 1990s. He was first elected to the **Maryland House of Delegates** in 1964 and became a **state senator** in 1975. The American Optometric Association named him the **country's top optometrist** in 1968.

Today's aging **U.S. workers** aren't fully taking advantage of their company **vision benefits**, leaving themselves at higher risk for age-related vision problems, eye diseases and chronic conditions that impact eye health and compromise productivity, according to the annual **Employee Perceptions of Vision Benefits** survey conducted by Transitions Optical. Baby boomers are only slightly more likely than younger employees to enroll in their vision benefit (79% vs. 75%). Similarly, 34% of baby boomers and 23% of those ages 65+ who enroll don't utilize their benefit to receive a **comprehensive eye exam**.

Virginia O.D.s Confront Definition of Surgery Bill

If passed, the legislation would have set the profession back by a number of years. **By John Murphy, Managing Editor**

Optometrists in Virginia recently dodged a bullet that would have made it illegal for O.D.s in the state to perform minor surgical procedures.

At the request of the Medical Society of Virginia, state legislators introduced a bill in early January to amend the state's definition of surgery and who could perform it.

"As originally introduced, the bill could have removed a number of procedures from Virginia optometrists' current scope of practice and set the profession back by a number of years," says Bo Keeney, associate director and legislative counsel of the Virginia Optometric Association.

The bill defined surgery as, "the incision, destruction or excision of tissue for the purpose of diagnostic or therapeutic treatment of conditions or disease processes by any instrument causing localized alteration or transposition of live human tissue."

Also, it specified that only doctors of medicine, osteopathy and podiatry, as well as dentists and nurse practitioners, could legally perform surgery. There was no mention of optometrists.

"We do not believe that the original bill as introduced was done with any malicious intent towards optometry. Unfortunately, intent does not always reflect all of the unintended consequences of a bill," Mr. Keeney says.

More than 300 optometrists made phone calls, wrote their legislators and got ready to visit the Virginia capital.

However, he added, "through a strong lobbying effort and a flood of over 300 optometrists who made phone calls, wrote their legislators and prepared to visit the capital, the bill was amended."

Passed by both the state Senate and House in mid-February, the bill now clarifies that the definition of surgery does not include certain procedures: removal of superficial foreign bodies, punctures, injections, dry needling, acupuncture and removal of dead tissue.

"We are happy to report that the substitute version of the bill … is a version that adequately protects Virginia's optometrists," Mr. Keeney says.

The governor is expected to sign the bill later this year.

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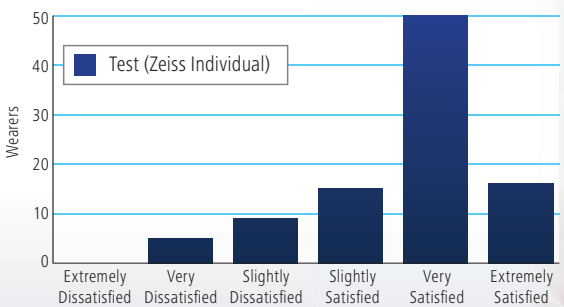

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Avastin-Related Endophthalmitis Was From Tainted Syringes, Study Says

News of *Streptococcus* endophthalmitis contamination following the intravitreal injection of Avastin (bevacizumab, Genentech) seemed to keep popping up last year, but no clear cause had been identified.

However, a recent study by researchers at the Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, seems to be hot on the trail of the culprit, at least in the Florida outbreak cases.[1]

Avastin, used off-label, is as effective at treating AMD as FDA-approved Lucentis (ranibizumab, Genentech), but costs significantly less per dose.[2] The cost-cutting, compounding procedure is common at VA hospitals across the nation.

A lawsuit against the U.S. Department of Veterans Affairs claimed that five individuals received a bacteria-tainted shot of the drug at the VA hospital in Nashville in March 2011. The complaint asserted that bacteria-tainted bevacizumab caused blindness and brain damage in one of the patients who received the injection. At least one doctor stated that the medication became contaminated while being mixed inside the hospital pharmacy.

Other reports indicate that five patients with macular degeneration were blinded last August at the VA Sepulveda Ambulatory Care Center in California after receiving injections of Avastin believed to have come from the pharmacy at the main campus of the VA Greater Los Angeles Healthcare System.

Later that month, the FDA issued a warning that at least 12 patients in the Miami area had been infected with *Streptococcus* endophthalmitis from injections of the drug. Investigators traced the tainted injections to a single pharmacy that had distributed the Avastin to multiple eye clinics.

A recent report investigated the 12 patients who presented with endophthalmitis after intravitreal bevacizumab injection.[1] The injections occurred at four different locations in south Florida during one week in early July 2011. While none of the infections originated at the Bascom Palmer Eye Institute, nine patients presented to its tertiary-care ophthalmic emergency room for treatment, and three were seen in consultation.

Microbiology cultures for 10 of the patients were positive for *Streptococcus mitis/oralis* and seven unused syringes of bevacizumab prepared by the compounding pharmacy at the same time as those prepared for the affected patients also were positive for *S. mitis/oralis*. After four months of follow-up, all but one patient had counting fingers or worse visual acuity, and three required evisceration or enucleation.

Local, state and federal health department officials have been investigating the source of the contamination, but the study authors believe the most likely cause was contamination during syringe preparation at the compounding pharmacy.

1. Goldberg RA, Flynn HW, Isom RF, et al. An outbreak of Streptococcus endophthalmitis after intravitreal injection of bevacizumab. Am J Ophthalmol. 2012 Feb;153(2):204-08.
2. CATT Research Group, Martin DF, Maguire MG, et al. Ranibizumab and bevacizumab for neovascular age-related macular degeneration. N Engl J Med. 2011 May 19;364(20):1897–1908.

New Preservative-free Prostaglandin Approved

The FDA has approved Zioptan (tafluprost 0.0015%, Merck), the first preservative-free prostaglandin analog. Zioptan is indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Its approval was based on efficacy and safety results from five controlled clinical studies in 905 patients, using both preservative-containing and preservative-free formulations.

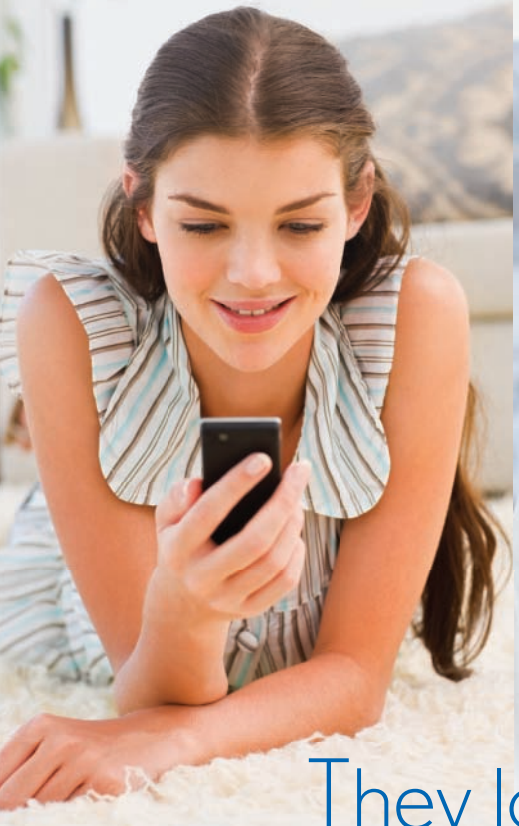
These studies showed that Zioptan, dosed once daily in the evening, lowered IOP by 6mm to 8mm Hg at three months and by 5mm to 8mm Hg at six months, from a baseline pressure of 23mm to 26mm Hg

Use of Zioptan may gradually change eyelashes in the treated eye, Merck noted. Changes include increased length, color, thickness, shape and number of lashes—these are usually reversible upon discontinuation of treatment. Other common side effects include increased pigmentation of the iris and redness in the eyes.

Merck expects Zioptan will be available in March, and will cost $97 for a 30-day supply.

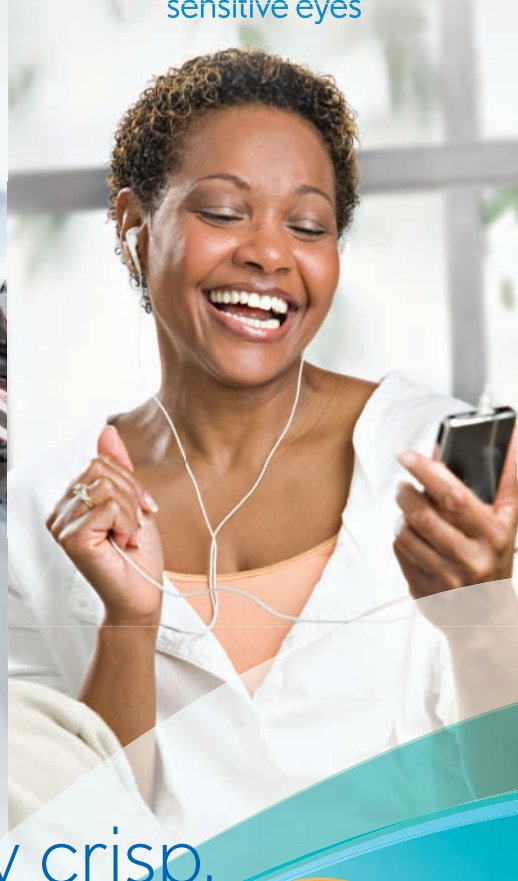
What do all these patients have in common?

First-time wearers



Wearers with astigmatism

Wearers with sensitive eyes



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75% of **existing wearers** agree they deliver **superior vision**[2]

78% of **sensitive eye wearers** rate them **comfortable on insertion**[2]

[1] Results from a 21-investigator, multi-site study of PureVision2 HD contact lenses. After 14 days of daily wear, subjects completed an online survey regarding lens performance. A total of 225 new-to-contact lens subjects completed the survey. Consumers rated the extent to which they agreed or disagreed with performance attributes that used a 6 point scale (1 = strongly disagree and 6 = strongly agree).

[2] Results from a 21-investigator, multi-site clinical study of PureVision2 and PureVision lenses. After 7 days of daily wear, subjects completed an online survey regarding lens performance. A total of 339 subjects completed the survey. Consumers rated the extent to which they agreed or disagreed with performance attributes that used a 6 point scale (1 = strongly disagree and 6 = strongly agree).

BAUSCH + LOMB

Gene Therapy for Leber's Saves Sight

A novel form of gene therapy improved the vision of three patients with congenital blindness when treated in their second eye. The study, published in *Science Translational Medicine*, reported that the patients were able to see in dim light and two could navigate obstacles in low-light situations after receiving the same treatment in the other eye.

Scientists from the Perelman School of Medicine at the University of Pennsylvania and The Children's Hospital of Philadelphia (CHOP) led the study, which targeted Leber's congenital amaurosis (LCA). The researchers injected patients with an adeno-associated viral vector that carried a normal version of the RPE65 gene, which is mutated in one form of LCA. Neither treatment triggered an immune reaction that cancelled the benefits of the inserted genes.

The researchers previously conducted a clinical trial of this gene therapy in 12 patients with LCA; four of them were children aged 11 and younger at the time of treatment. The researchers had treated only one eye—the one with worse vision. Six of the patients experienced improved vision enough to no longer be classified as legally blind.

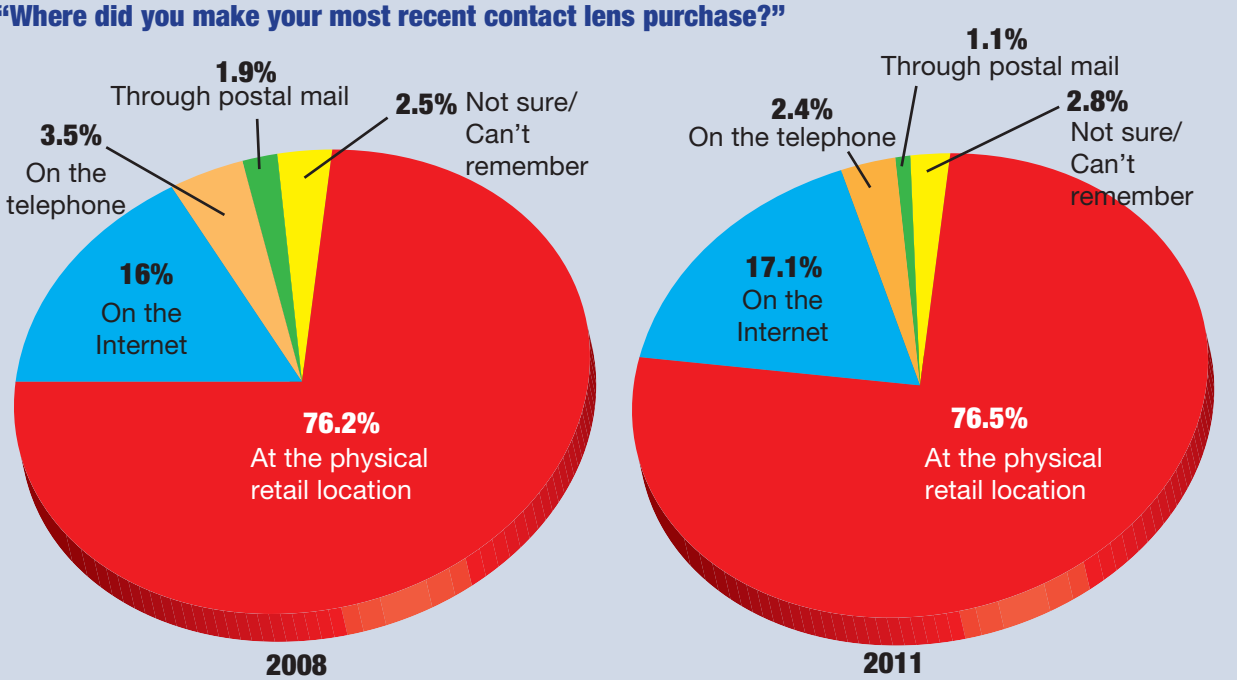
"Patients have told us how their lives have changed since receiving gene therapy," says study co-leader Jean Bennett, M.D., Ph.D., F.M. Kirby professor of ophthalmology at Penn. "They are able to walk around at night, go shopping for groceries and recognize people's faces—all things they couldn't do before. At the same time, we were able to objectively measure improvements in light sensitivity, side vision and other visual functions."

Other objective results came from brain signals seen on neuroimaging. When a dimly-flickering checkerboard pattern flashed in front of a patient's recently treated eye, an area in the brain responsible for vision lit up during functional magnetic resonance imaging (fMRI).

"This finding is telling us that the brain is responding to the eye's sensitivity to dim light," says Manzar Ashtari, Ph.D., a radiology researcher at CHOP and the study's co-leader.

Bennett J, Ashtari M, Wellman J, et al. AAV2 gene therapy readministration in three adults with congenital blindness. Sci Transl Med. 2012 Feb 8;4(120):120ra15.

"Where did you make your most recent contact lens purchase?"



Jobson Research's *2011 Contact Lens Wearers Insight Survey* asked nearly 1,600 current contact lens wearers where they last bought their contact lenses. Notice that the numbers haven't changed much in the past three years.

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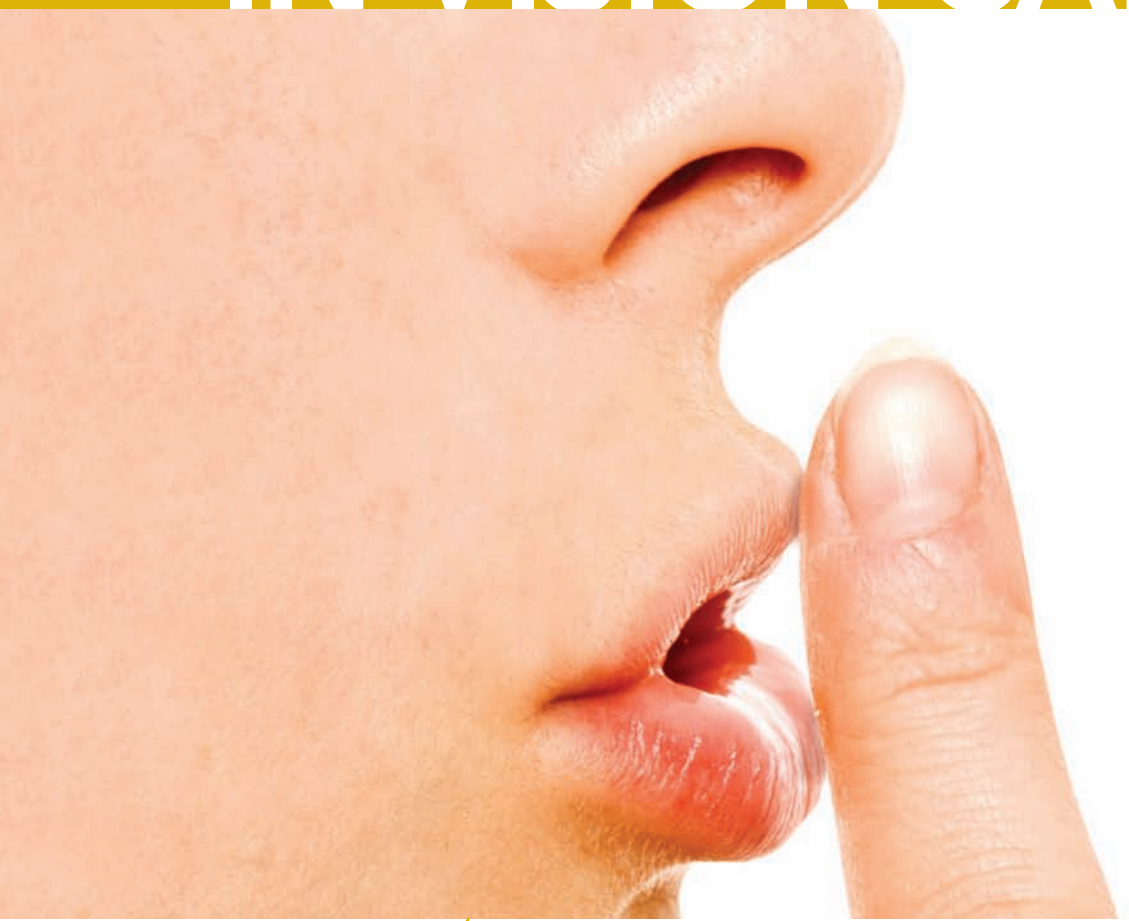

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Vets Remove Jumbo-sized Cataract

The North Carolina Zoo's longest resident, a 38-year-old African elephant named C'sar, had been suffering from deteriorating vision since 2010 due to cataracts in both eyes. His condition became so bad that he was taken out of the elephant exhibit for his own safety, and sheltered within his barn and paddock since March 2011, out of the public eye.

But in November 2011, the well-known pachyderm successfully underwent cataract surgery in his left eye, thanks to a team of specialists from the N.C. State University College of Veterinary Medicine.

Led by Richard J. McMullen, Jr., D.V.M., assistant professor of ophthalmology, the four-hour procedure was the fifth cataract surgery performed on an elephant anywhere in the world. It also marked the first time spectral-domain optical coherence tomography was used on an elephant.

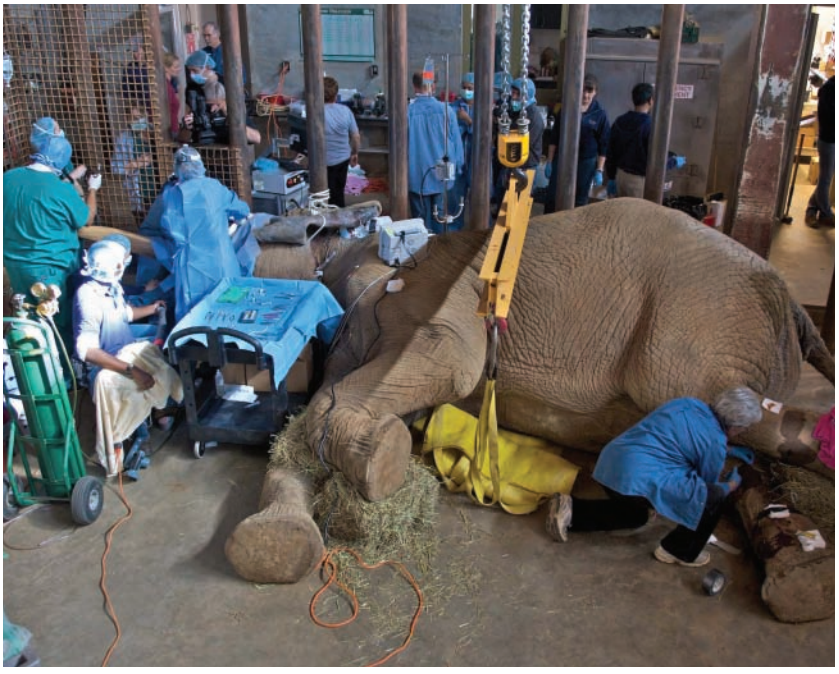
The surgery team utilized a specialized ophthalmic imaging system, the Envisu R2300 [Bioptigen], the only commercially available ophthalmic SD-OCT system with a hand-held scanner.

Unfortunately, the surgery left C'sar aphakic. Because of damaged tissue caused by the cataract, the elephant's eye would not have provided enough support for the specially-created artificial lens that Dr. McMullen had intended to implant.

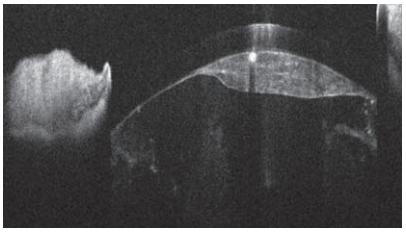
Although C'sar's vision is now improved after cataract removal, he'll be farsighted without the implant in that eye.

Nevertheless, "C'sar's surgery was highly successful and has dramatically improved his quality of life, even without the replacement lens," says Guy Lichty, the zoo's mammal curator.

The zoo staff looks forward to allowing C'sar to return to a larger exhibit space once the weather and his recovery allows it. But if the elephant still has problems safely negotiating the space, "we'll have to discuss perhaps operating on his other eye in hopes of further improvement," Mr. Lichty says.



Imagine comanaging care for this critter. C'sar, a 38-year-old pachyderm, undergoes a four-hour cataract procedure in the North Carolina Zoo's elephant barn.



This SD-OCT image (above) of C'sar's cataract chronicles the first time spectral domain was used on an elephant. Veterinary ophthalmologists had hoped to implant a specially created artificial lens in C'sar's eye, but damaged tissue could not support it. It would have been the first artificial lens implantation ever performed on an elephant.

Symptomatic VMA

A Disease That's Gaining Traction

Symptomatic vitreomacular adhesion (VMA) is an increasingly recognized sight-threatening disease of the vitreoretinal interface[1]

VMA:

- » May lead to symptoms such as metamorphopsia, decreased visual acuity, and central visual field defect[2]
- » Can cause traction resulting in anatomical damage, which may lead to severe visual consequences, including[3,4]
  - Macular hole[3]
  - Retinal tear/detachment[4]

For more information, visit: **www.SymptomaticVMA.com**

REFERENCES

1. Schneider EW, Johnson MW. Emerging nonsurgical methods for the treatment of vitreomacular adhesion: a review. *Clin Ophthalmol.* 2011;5:1151-65. **2.** Steidl SM, Hartnett ME. Clinical pathways in vitreoretinal disease. New York: *Thieme Medical Publishers;* 2003. Chapter 17; 263-86. **3.** Gallemore RP, Jumper JM, McCuen BW 2nd, Jaffe GJ, Postel EA, Toth CA. Diagnosis of vitreoretinal adhesions in macular disease with optical coherence tomography. *Retina.* 2000;20(2):115-20. **4.** Mitry D, Fleck BW, Wright AF, Campbell H, Charteris DG. Pathogenesis of Rhegmatogenous Retinal Detachment: Predisposing Anatomy and Cell Biology. *Retina.* 2010 Nov–Dec;30(10):1561–72.

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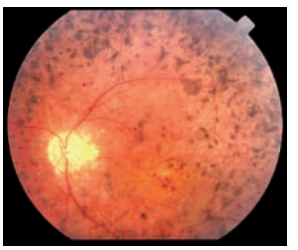
Omega-3 and Vitamin A Slow RP Vision Loss

A combination of omega-3 fatty acids and vitamin A can slow the progression of retinitis pigmentosa (RP) in adults, according to a study in the February 13 online edition of *Archives of Ophthalmology*.

In this study, the researchers evaluated 357 patients with RP who took 15,000 IU of vitamin A per day for four to six years. The researchers instructed the patients to complete dietary questionnaires, which were used to gauge the participants' average daily omega-3 fatty acid intake.



Omega-3s appear to enhance Vitamin A, which slows down retinitis pigmentosa.

They determined that patients who had diets rich in long-chain omega-3 fatty acids (consumption of at least 0.20g per day) experienced a 40% slower decline in distance visual acuity and a nearly 50% slower decline in central visual field sensitivity than those with diets low or deficient in omega-3s.

The researchers concluded that, with adequate vitamin A supplementation and omega-3 fatty acid intake, patients with RP should be able to retain both visual acuity and central visual field function throughout most of their lives.

"A representative patient who starts receiving vitamin A by age 35 years and eats an omega-3-rich diet (e.g., one to two 3oz servings of oily fish per week) with an Early Treatment of Diabetic Retinopathy Study (ETDRS) acuity of 50 letters would, on average, be expected to decline to an ETDRS acuity of 24 letters at age 79—whereas, this patient receiving vitamin A with a low dietary omega-3 intake (e.g., less than one 3oz serving of oily fish per week) would decline to this level at age 61," wrote the authors.

"Patients are advised to take vitamin A to replace their rods and eat oily fish to enhance delivery of vitamin A to cones," says lead author Eliot L. Berson, M.D., professor of ophthalmology at Harvard Medical School and the Massachusetts Eye and Ear Infirmary in Boston, explaining in shorthand why it's beneficial for RP patients to increase their intake of both vitamin A and omega-3 fatty acid.

Dr. Berson elaborates, "With respect to vitamin A, we and others have suggested that, under daylight conditions, rods give cones vitamin A via Mueller cells. Interphotoreceptor retinoid binding protein (IRBP) transports vitamin A between these cells, and the release of vitamin A from IRBP requires DHA [which is] present in oily fish." He adds, "Rod degeneration leads to a deficiency of vitamin A and DHA. This could explain why vitamin A plus an oily fish diet benefits patients with RP." ■

Berson EL, Rosner B, Sandberg MA, et al. ω-3 intake and visual acuity in patients with retinitis pigmentosa receiving vitamin A. Arch Ophthalmol. 2012 Feb 13. [Epub ahead of print]

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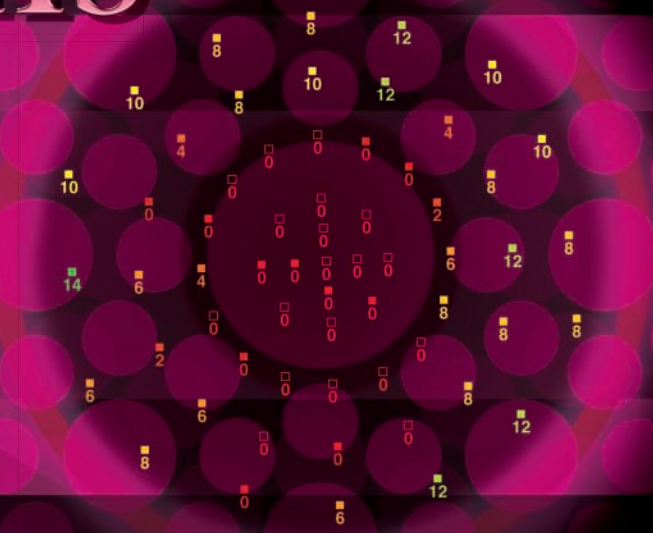

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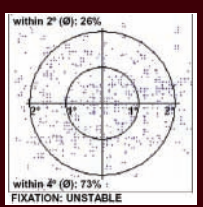

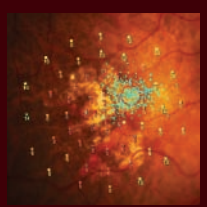

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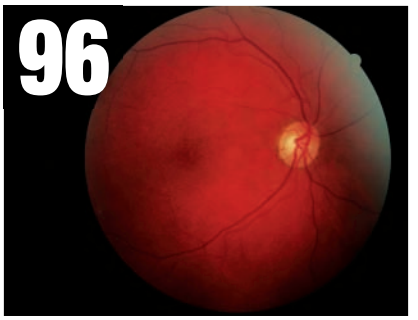

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE
PATADAY™ solution is a mast cell stabilizer indicated for the treatment of ocular itching associated with allergic conjunctivitis.

DOSAGE AND ADMINISTRATION
The recommended dose is one drop in each affected eye once a day.

DOSAGE FORMS AND STRENGTHS
Ophthalmic solution 0.2%: each ml contains 2.22 mg of olopatadine hydrochloride.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
For topical ocular use only: not for injection or oral use.

Contamination of Tip and Solution: As with any eye drop, to prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Contact Lens Use: Patients should be advised not to wear a contact lens if their eye is red. PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% should not be used to treat contact lens related irritation. The preservative in PATADAY™ solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and whose eyes are not red, should be instructed to wait at least ten minutes after instilling PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% before they insert their contact lenses.

ADVERSE REACTIONS
Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%. The following ocular adverse experiences were reported in 5% or less of patients: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus. The following non-ocular adverse experiences were reported in 5% or less of patients: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, rhinitis, sinusitis and taste perversion. Some of these events were similar to the underlying disease being studied.

USE IN SPECIFIC POPULATIONS
Pregnancy: Teratogenic effects: Pregnancy Category C. Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the MROHD and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of olopatadine during organogenesis showed a decrease in fetal weight. Further, rats treated with 600 mg/kg/day of olopatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Nursing Mothers: Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY
Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µL drop size and a 50 kg person, these doses were approximately 150,000 and 50,000 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of approximately 100,000 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of approximately 15,000 times the MROHD level.

U.S. Patents Nos. 5,641,805; 6,995,186; 7,402,609

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To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep the bottle tightly closed when not in use.

PATADAY™ Solution should not be used to treat contact lens-related irritation. The preservative in PATADAY™ Solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses should be instructed to wait at least ten minutes after instilling PATADAY™ Solution before they insert their contact lenses.

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

For additional information about PATADAY™ Solution, please refer to the brief summary of prescribing information on the following page.

*Post-hoc analysis of combined data from two studies using a contralateral conjunctival allergen challenge (CAC). Based on a scale of itching scores of 0-4, with 0 as no itching and 4 as severe itching. Ocular itching was evaluated 3 minutes after allergen challenge at onset and at 16 hours.

†(N=85; 95% CI=48.8, 70.5) ‡(N=82; 95% CI=48.3, 70.4)

References: 1. IMS Health, IMS National Prescription Audit™, August 2010 to February 2011, USC 61500 OPHTH ANTI-ALLERGY. **2.** Data on file.

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Letters to the **Editor**

Cataract Surgery Can Be Glaucoma Cure

Twenty-plus years ago, I attended a continuing education seminar near Dallas where one of the speakers was a professor from the University of Houston College of Optometry. He began by saying something to the effect that, "the more we learn about glaucoma, the less we know." He then followed up by stating that glaucoma may be several different diseases lumped together under one name. He continued by discussing open angle glaucoma, closed angle glaucoma, normal pressure glaucoma, and so on.

When I Googled a definition for glaucoma, I first got, "A condition of increased pressure within the eyeball, causing gradual loss of sight." Further down was the medical dictionary definition: "a group of eye diseases characterized by damage to the optic nerve usually due to excessively high intraocular pressure (IOP)." And another entry stated, "a common eye condition in which the fluid pressure inside the eye rises because of slowed fluid drainage from the eye." There are lots of other entries basically saying the same things. But, other than closed angle glaucoma, there is not much about the cause of glaucoma. The "cause" is listed as unknown or, at best, increased inflow or decreased outflow of fluids.

I had not heard that lens exchange could be a first-line treatment for ocular hypertension and/or adult glaucoma. This appears pretty straightforward, so why haven't I been hearing and reading about it?

Drs. Brooks J. Poley, Richard L. Lindstrom, Thomas W. Samuelson, and Richard R. Schulze, Jr., have identified one cause of increased IOP and a way to reduce it. It is established that the crystalline lens continues to grow throughout one's entire life.[1,2] This "lens growth repositions the anterior lens capsule and the anterior uvea (iris and anterior ciliary body) forward, compressing the trabecular meshwork and the canal of Schlemm, so intraocular pressure elevates."[3] This becomes ocular hypertension and usually glaucoma thereafter.

They did retrospective reviews and found that phacoemulsification with intraocular lens implantation did in fact significantly lower IOP. An obvious conclusion is that, "the aging crystalline lens may be a major cause of ocular hypertension and glaucoma," and lens exchange surgery certainly has the potential to delay or prevent the development of adult glaucoma.[4] Further, their studies "suggest phaco/IOL can be an effective treatment for glaucoma eyes if a target IOL of 18mm Hg following surgery is deemed adequate."[5]

Prior to meeting Dr. Poley, I had not heard of nor read in any of our journals that lens exchange could be a first-line treatment for ocular hypertension and/or adult glaucoma. This appears pretty straightforward, so why haven't I been hearing and reading about it? There is no way that I could know the

Sight **Gags**

By Scott Lee, O.D.

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answer to that question. However, I am not shy about guessing:

• The FDA has not given its blessing to phaco/IOL as an approved treatment for ocular hypertension and/or glaucoma. Therefore, it does not have the important "standard of care" designation.

• While numerous meds are prescribed and procedures performed "off label," the medical community is often slow to accept something totally different from what it has been doing.

• The glaucoma pharmaceutical industry generates at least $3 billion-plus, and lens exchange surgery could make a big dent therein.

• There would be a far smaller need for "glaucoma specialists" (M.D.s, D.O.s, and O.D.s) and many would lose their income for managing glaucoma patients.

All activity has some risk. This includes phaco/IOL surgery. Phaco/IOL surgery is the most frequently performed surgery in America, and the risk seems to be miniscule. Many refractive surgeons have stated that they believe phaco/IOL surgery yields better outcomes than LASIK and PRK.

It has been stated that everyone who lives long enough will develop cataracts (impossible to either prove or disprove), so if one is interested in refractive surgery, why have two surgeries? While there are currently only three progressive/bifocal/ accommodating FDA-approved IOLs, there are many others in the pipeline, with more to follow. Add in the avoidance of glaucoma, and phaco/IOL surgery appears very attractive. So attractive, in fact, that I believe in 10 or 15 years, refractive surgery will shift from LASIK/ PRK to phaco/IOL. LASIK/PRK provides excellent results for either distant or near vision, but not both.

Phaco with multifocal IOL implantation provides excellent near and distant vision, prevents ocular hypertensive eyes from converting to glaucoma eyes, lowers intraocular pressure in eyes with glaucoma, and removes the cataract from those who live long enough for it to develop.

—John Clark Moffett, O.D.
Carrollton, Texas

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Eyesight and the Eye Chart

Would you believe that the eye chart that was introduced more than 150 years ago (1862 to be exact) is still present in every medical office in the world! It is still being used as a screening device for seeing disorders. Before the Snellen eye chart was developed, there was no means to measure what the eyes could see at great distances.

But it is the same 150+ year-old eye chart that is still being used to determine seeing problems of the young and old. How far away one can see has very little to do with today's school problems, computer problems or work problems. The eye chart is a monocular test for far-away seeing. It has little to do with reading difficulties. It does give a false sense of security in what the two eyes can see.

Can you imagine any other assessment for health screening that uses a test that is more than 150 years old and presents mostly false positives for what it tests?

According to an NIH study, even trained health screeners still miss 30% of children's vision disorders. Amblyopia, strabismus and refractive errors were consistently missed during the study's screening process.

Can you imagine what the eye chart *cannot* do? ■

—Sol Tannebaum, O.D.
Olympia Fields, Ill.

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Rethinking Comanagement

This month's report describes a new model, called Integrated Eye Care.

By Amy Hellem, Editor-in-Chief

I often hear optometrists grumble that they wouldn't recommend going to optometry school to their own friends and family. "Private practice is dying," they say. And, "the new O.D.'s brightest career option is employment in a chain."

Indeed, there is tremendous change in the way optometry is practiced. The solo O.D. practice is quickly becoming a thing of the past. However, I disagree with the pessimists who maintain that Walmart and Sears are the pie in the sky for every new grad.

Put yourself in your patients' shoes and consider where you turn for goods and services. Because we know we can rely on one-stop-shopping at Home Depot and Lowes, for example, most of us who live in cities or suburbia rarely frequent the local hardware store, even if there is still one in town.

Similarly, we associate quality and a more progressive approach from doctors who practice under the banner of universities or large medical centers. It's not a matter of bigger-is-better; it's simply a modern-day reality that patients feel safer when there is a perceived system of checks and balances. That is why, as an optometrist, your relationship with your comanaging ophthalmologist is becoming increasingly important. But what should that relationship be?

In this month's Comanagement Report, Derek N. Cunningham, O.D., and Walt Whitley, O.D., M.B.A., describe a system they refer to as "Integrated Eye Care" (see What is Integrated Eye Care, page 64). Drs. Cunningham and Whitley explain why and how integrated eye care has developed in the United States and what key benefits and limitations this practice model includes.

If you've never heard of integrated eye care before, you're not alone. However, you may be following the model without even knowing it! An integrated eye care practice can take many forms, the authors say. They describe four basic models:

- Optometrists in private practice who actively comanage patients.
- Optometrists who work directly with ophthalmologists in a referral center.
- Optometrists who partner/employ/lease space with ophthalmologists.
- Optometrists who practice in a vertically integrated setting (O.D./M.D./optical).

The authors describe several advantages to integrated eye care delivery. Most importantly, integrated eye care utilizes the strengths of each practitioner, improves efficiency in patient care, and establishes a natural checks-and-balances system. It also enhances profitability. The authors have also profiled an extensive and diverse group of practicing optometrists who practice under an integrated eye care model. Each profiled doctor shares his or her thoughts on the key benefits and limitations of the model in their own setting. I urge you to read this insightful article. ■

Amy Hellem
Editor-in-Chief

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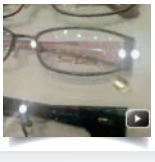
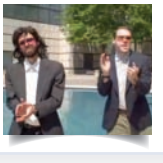
A new app promises to boost the performance of the brain's visual cortex, thus leading to vision improvements.



Find out why many Canadians are overpaying for prescription glasses.



This UAB Optometry Class of 2009 "Script in a Box" video is a must-see for Saturday Night Live fans.

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A Word to the Wise

Wisdom comes from messing up. My new grandson makes a lot of messes, which we clean up for him. He's just about the wisest guy I know. **By Montgomery Vickers, O.D.**

My daughter had her first child (my third grandchild, Max!) on January 23, 2012. A couple of days later, she was having a moment of angst. I explained to her that all parents have this out-of-control feeling and it will totally clear up in the next 35 years or so. My children are 28 and 29, so I'm still a little jumpy myself.

After my short but sweet monologue about the joys of changing poopy diapers and painful nursing, my lovely daughter said to me, "You're wise, dad." It made me think about losing my own father many years ago. (I had asked him at that moment for his wisdom. Maybe he heard?)

Anyway, I've always felt that wisdom is directly related to making mistakes and learning from them. Oh, occasionally we accidently do something right and remember how to do it again. But, by far, it's our weak moments that evolve into strengths.

We prove that in our practices daily and, yes, there is a reason that they call it "practice." We never quite perfect it…we're always learning. I can remember when I thought it made good sense to tell the patient every single detail:

"OK, Mrs. Mightberight, let's take a walk through your eyes. These are your eyelashes. They are brown. They protect your eye from dust and debris. They offer some shade and protection in bright sunlight…Let's count 'em!"

Then, 26 minutes later, "These are your puncta…"

Can you guess that my patients thought I was goofy? It probably clicked in somewhere around, "This is your Mittendorf dot…"

Another bit of wisdom that I'm still working on: Patients who skip appointments don't really want me to keep bugging them to come in. For example, when a diabetic patient misses a couple of appointments, I become partially crazed. I e-mail. I write personal notes. I explain in minute detail that blindness is a possible outcome in diabetes. I recount how diabetes caused a stroke that blinded my father.

It only ticks them off. I have literally tried such brilliant ideas as:

1. Writing a monthly proactive note after the exam telling them "only 11 months left until your next diabetic eye examination," and later, "only seven more months," and so forth. They hated me for it almost as much as when I wrote them a note every month for 10 years after they neglected to show up in the first place.

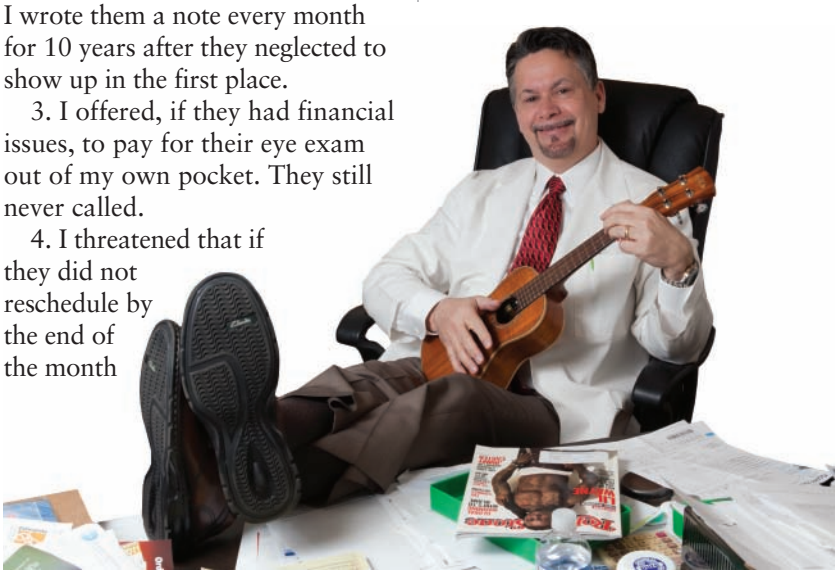
3. I offered, if they had financial issues, to pay for their eye exam out of my own pocket. They still never called.

4. I threatened that if they did not reschedule by the end of the month I would never, ever speak to them again! Boy, were they thankful.

Wisdom takes time, especially if the person wanting to be wiser starts from a position of resolute goofiness. It can be a challenge to move beyond goofy. Trust me.

The problem is this: I always thought that "wise" meant "perfect." In optometry, there is no such thing as perfect, although I have met quite a few colleagues who feel, deep down inside, that they are pretty darn close.

The truly wise optometrist can admit his or her foibles. This doctor is often unassuming but, when consulted, is very often helpful and correct. He or she has learned from past mistakes and, thus, became wise. In some ways, the doctors who mess up the most have more room to become wise, right? So, based upon my mistakes, I must be a freakin' sensei by now! ■



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The Chaos of Comanagement

Comanagement is for more than cataract surgery. It's for any surgical procedure with a global period of 10 days or longer. **By John Rumpakis, O.D., M.B.A., Clinical Coding Editor**

Comanagement is a nonfinancial arrangement between a physician who performs surgery and a comanaging physician who provides care to the patient for some portion of the global follow-up period. The physician who performs the surgical procedure is usually an M.D., but in some cases is an O.D. The comanaging physician can be either an M.D. or an O.D., as well.

The comanagement of any surgery begins with the formal transfer of care from the surgeon to the comanaging physician—typically to the physician who originally referred the patient for a surgical evaluation. However, a referral to a surgeon *cannot* be based upon the requirement that the surgeon refer the patient back to the referring physician.

In a comanagement situation, it's the patient who is actually the one to choose the comanaging physician. Be sure to discuss the comanagement arrangement with your patient before the initial surgical evaluation. Above all, the patient's wellbeing is the most important factor to consider in any surgical referral and comanagement arrangement.

Each physician plays a key role and has certain protocols to follow. Have a clear agreement in place with the surgeon to establish the guidelines for communication, for timely reports back to the surgeon, and when the patient will be seen again after the surgery. The surgeon should provide information on the surgery claim filed, so the correct information for the postoperative care claim can be used.

Each regional Medicare carrier may have its own policies for comanaged arrangements in local coverage determinations, which need to be followed when performing and filing postoperative care. But, some basic rules are common when billing for this care:

- When providing preoperative care, file the appropriate CPT code with the -54 modifier to indicate preoperative care only.
- When providing postoperative care, file the appropriate CPT code with the -55 modifier to indicate postoperative care only.
- Indicate the specific eye using the -RT or -LT modifier.
- When a second surgery is performed during the postoperative period of the first surgery, the -79 modifier is used to indicate that the filing is for an unrelated procedure or service by the same physician during the postoperative period. The surgeon's name and National Provider Identifier (NPI) number must also be listed on the claim.

The Postoperative Period: Always 90 Days?

Each surgical procedure has a specific global or postoperative period. Ninety days is common, particularly for cataract surgery. However, a procedure like punctal occlusion has a global period of 10 days. The physician responsible for the postoperative period is expected to provide all postoperative care during this designated period without billing extra fees.

But, if a patient develops a new medical condition that is unrelated to the surgery during the postoperative period, that care is not considered part of the postoperative care. This unrelated care can be billed separately using the -24 modifier for office visits or the -79 modifier for new surgical procedures (such as a foreign body removal).

However, if a complication of the surgery occurs, the care for this complication is considered a part of the postoperative period and cannot be billed separately.

The Centers for Medicare & Medicaid Services generally calculates the reimbursement fee for comanagement at 20% of the total allowed fee for the surgery if care is provided for the entire postoperative period. But, this total percentage can vary based upon the procedure; otherwise, the reimbursement fee is prorated based upon the number of days that care is actually performed during the postoperative period. Some private insurers and Medicare Advantage plans may use a different calculation, so be sure to know before you provide postoperative care. ■

Please send your comments to CodingAbstract@gmail.com.

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At the annual meeting of the American Academy of Ophthalmology in October 2010, Dr. Marguerite McDonald presented a poster on Varilux Physio Enhanced™ lenses with W.A.V.E. Technology 2™—a progressive addition lens (PAL) design that incorporates pupil size modeling data for improved low-light vision.

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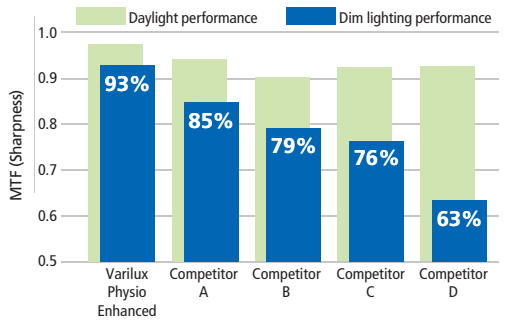
These wearer-comparison outcomes corroborate optical bench test results that showed the Varilux Physio Enhanced lens exhibited reduced wavefront aberration levels and improved contrast function when compared to four other progressive lenses of identical prescription and material.

Comparison of Visual Sharpness in Low-light vs Bright-light Conditions

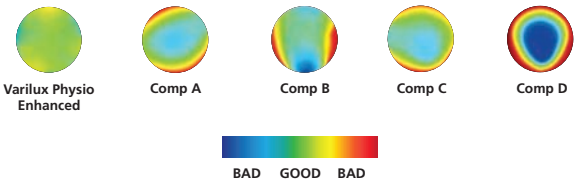


The Varilux Physio Enhanced lens maintained better contrast sensitivity in both low-light and bright-light conditions as indicated by a higher modulation transfer function (MTF).

These tests showed Varilux Physio Enhanced offered:

- The lowest level of aberration in the portion of the lens utilized
- The highest modulation transfer function in dim and standard lighting

Comparison of Wavefront Aberration Levels



The Varilux Physio Enhanced lens exhibited lower aberration levels than designs that do not account for the effect of pupil size variation on progressive lens performance.

Conclusions

Cumulative results from a double-masked wearer study and optical bench testing indicate that the Varilux Physio Enhanced lens, which is designed to account for the natural changes in pupil size that occur in response to lighting levels and the individual's accommodative state, provides improved vision in low-light conditions when compared to progressive lenses that do not incorporate pupil size modeling data into their design.

The data show that the Varilux Physio Enhanced lens:

- Is globally preferred, with preference achieving statistical significance in dim light situations
- Has fewer aberrations than other progressive designs tested
- Preserves 93% of image sharpness in dim light for improved contrast sensitivity

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Clinical Pearls in Seasonal Allergy Management

By Jimmy D. Bartlett, O.D., D.Sc., F.A.A.O.

It's allergy season 2012—time to prepare for the onslaught of patients with red, itchy eyes. Fortunately, there are several new ophthalmic products specifically formulated for the treatment of seasonal allergic conjunctivitis (SAC). In this article, I will review some of the most important and practical tips and precautions that should be of significant benefit to your allergy patients during the next several months.

Allergy Presentation

Of the four main types of ocular allergy—SAC, giant papillary conjunctivitis, vernal conjunctivitis and atopic conjunctivitis—SAC is the most common, accounting for the majority of our allergic patients. Although the diagnosis of SAC can be relatively straightforward, with itching as the hallmark symptom, not every patient with itching has allergic conjunctivitis. It's important to remember that itching can also be a symptom in patients with dry eye, meibomian gland dysfunction, all forms of anterior blepharitis, and other conditions. Take note, however, that if there is no itching, the patient most likely does not have allergic conjunctivitis.

In some rare cases, clinical signs and symptoms alone may not be enough to make the correct diagnosis, and allergen skin prick testing, IgE titers in tears, and conjunctival smears to uncover eosinophils may be needed.[1] Because many optometrists are not prepared to do this, referral to an allergist may be needed.

Tailored Treatments

For patients with very mild or intermittent symptoms of itching, preservative-free artificial tears can dilute the antigenic stimulus and relieve symptoms without inducing any drug toxicity at very low cost. These patients, as well as more symptomatic individuals, also can often benefit from the application of cold compresses several times during the day, if practical. This is especially beneficial for symptoms of itching, but it is not effective for the conjunctival hyperemia that is associated with the condition.

When selecting pharmacologic interventions, choose medications with dosing frequencies of only once or twice daily. These dosing regimens apply to all of the newer "dual-mechanism" (antihistamine plus mast cell stabilization) agents and partially account for these drugs' popularity compared to the older ocular antihistamines and mast cell stabilizers that required q.i.d. therapy. Just remember that some patients will have "breakthrough" symptoms and may need an additional drop during the day. Don't hesitate to advise the patient to use additional drops as needed.

In contrast to the conventional dual-mechanism drugs, when topical steroids are used, it is extremely important to pulse dose them every one to two hours while awake for the first 24 hours. Then, the dosage may be decreased to four times daily for at least one week. This approach will jumpstart the anti-inflammatory process, and is significantly more effective than less aggressive dosing.

Although systemic antihistamines, such as loratadine (e.g., Claritin, Schering-Plough), are effective in the treatment of many allergic conditions, optometrists generally should avoid recommendation of these agents. With as little as four days of once-daily dosing, oral loratadine is often associated with the clinical signs of ocular dryness, including decreased tear volume and tear flow. Also, loratadine can increase fluorescein staining of the cornea, indicating an increase in ocular surface damage, which exacerbates the ocular symptoms.[2]

Patanol (olopatadine 0.1%, Alcon) has proven to be an extremely effective and popular anti-allergy agent in optometric practice. Keep in mind that this agent can reduce ocular itching significantly better than a topical nonsteroidal anti-inflammatory drug.[3] What's more, Patanol can effectively suppress clinical symptoms when used at least two weeks prior to the onset of allergy season, so don't hesitate to use it early in patients who have a previous history of SAC.[4]

Trying Something New

We are fortunate to have two new dual-mechanism drugs that were FDA approved in the last few years—Bepreve (bepotastine besilate 1.5%, ISTA) and Lastacaft (alcaftadine 0.25%, Allergan). Bepotastine is a highly selective H1 antagonist with mast cell stabilizing and anti-inflammatory activity.[5] In both adults and children, this drug significantly reduces ocular itching within 15 minutes after dosing, but there is little effect on ocular redness.[5,6] For best results, the medication generally

Supported by an unrestricted grant from BAUSCH + LOMB

should be instilled b.i.d. A unique feature of this medication is that it can elicit a clinically meaningful reduction in non-ocular symptoms of allergy, especially nasal congestion and rhinorrhea, for at least eight hours following instillation.[7]

Alcaftadine, with an onset of action within three minutes and a duration of action of at least 16 hours, is also more effective for itching than ocular redness.[8] In a comparative study, alcaftadine 0.25% was shown to have effects on itching and redness similar to olopatadine 0.1%. [9] The practical difference, however, is that alcaftadine is dosed only once daily, while olopatadine requires twice-daily dosing. There have been no studies comparing alcaftadine to Pataday (olopatadine 0.2%, Alcon).

Special Circumstances

What would be the safest topical agent to prescribe in a pregnant patient with SAC? Among the contemporary, dual-mechanism anti-allergy drugs, only alcaftadine 0.25% carries the FDA pregnancy category B designation.[10] It is my first-choice drug in these circumstances.

What do you do if the patient complains bitterly about the cost of the prescribed medication? One option is to use the discount coupons that may be distributed by the pharmaceutical representatives. Another option is to recommend over the counter ketotifen 0.025%, which was originally approved by the FDA as Zaditor (CIBA Vision).

At least one of the generic formulations (Alaway, Bausch + Lomb) has been shown to be bioequivalent to the original Zaditor and thus can be recommended with confidence.[11] These OTC products may be comparable to olopatadine 0.1% in reducing itching associated with SAC, although possibly somewhat less comfortable.[12-14]

Ketotifen is an excellent treatment option for children, significantly inhibiting their ocular itching as well as reducing redness, chemosis and lid swelling. No untoward drug-related systemic events have been reported, and adverse ocular effects are insignificant.[15] Thus, OTC ketotifen can be a cost-effective and safe alternative for self-management of SAC in both adults and children.

Rethinking Steroid Treatment

Over the last six to eight years, there's been a paradigm shift in the treatment of ocular allergy. While it has been customary to initiate therapy with dual-mechanism drugs and then advance to steroids as second-line treatment, many patients are actually best served using steroids as first-line therapy. This is especially true for patients who have signs (redness, lid swelling, chemosis) in addition to symptoms (itching), or for patients who have experienced OTC failure. Although any topical steroid can be used, only Alrex (loteprednol etabonate 0.2%, Bausch + Lomb) has been specifically developed and FDA approved for the treatment of SAC.[16]

As a steroid, loteprednol offers the most comprehensive treatment of all the signs and symptoms of SAC. And it does so with a safety profile comparable to that of placebo.[17,18] Clinicians are often concerned about the side effects of steroids, such as elevation of intraocular pressure and development of cataract. It is important to note, however, that loteprednol 0.2% is a safe topical steroid even when used on a long-term basis for the treatment of SAC and perennial allergic conjunctivitis.[19]

Of course, IOP elevations are possible with any steroid, so patients should always be monitored closely during therapy.[20,21] My recommendation is to see the patient in two to four weeks after initiating therapy, and then every three to six months thereafter while on continuous steroid therapy. If the patient has not experienced an IOP elevation in the first four to six weeks of treatment, he or she is highly unlikely to be a steroid responder and can continue treatment.

Be very stingy with refill authorizations and requests from the patient. This will help to ensure that he or she actually returns for ongoing monitoring. Be sure to dilate the patient once annually to check for cataract formation. Fortunately, there have been no confirmed reports of posterior subcapsular cataract development associated with the use of loteprednol, but a dilated examination is standard of care for patients on long-term steroid therapy.

One final pearl: For patients with a history of severe seasonal allergies, the use of prophylactic (preseason) Lotemax (loteprednol 0.5%, Bausch + Lomb) can be extremely effective to reduce both signs and symptoms during allergy season.[22] Once the patient has been stabilized during the peak pollen season, he or she can then be switched to the 0.2% formulation (Alrex) or one of the dual-mechanism drugs to finish out the allergy season.

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When the Doctor Becomes the Patient

After an unexpected transient ischemic attack, an optometrist gets a new perspective on how it feels to be on the other side of the doctor-patient interaction.

By Cheryl G. Murphy, O.D.

An active 31-year-old female walks into your office with an unremarkable medical history; she's a nonsmoker who falls within a healthy weight range. She complains that recently she has seen a small, dark spot in her vision in one eye for a short period of time and has had a history of ophthalmic migraines in the past.

It would be tempting to assume that the "dark spot" she saw was just a poorly described ophthalmic migraine—so tempting to assume, that even I took the bait and diagnosed it as just that. That young, healthy 31-year-old woman was me. And it wasn't an ophthalmic migraine I was experiencing, it was a transient ischemic attack (TIA), also known as a mini stroke.

Although my experience was terrifying and unsettling, it gave me a better understanding of what it feels like to be on the other side of the patient-doctor interaction and has allowed me to improve communication and patient care in my practice.

How it Happened

I was at home making my kids their lunches when I saw a small distortion in my vision and thought, "Oh boy, here we go, another ophthalmic migraine." I cursed the fact that, for the next 20 minutes, my vision in that eye would soon become a swirling blur of zigzags and zebra stripes. The only weird thing was that the visual defect never radiated outward like the ophthalmic migraines I had experienced in the past. Its lack of expansion really didn't strike me as odd at the time, so I just continued on and finished up lunch.

About 10 minutes later, I was reading my son a book when my ability to read was suddenly turned off like a light switch. I was completely and instantaneously illiterate. I could see letters on the page. I could see that they were grouped into words. But I had no idea what those words were—it was as if they were written in a foreign language.

Frightened, I grabbed the phone and called my husband and other family members who lived nearby. They were alarmed, but assumed that I was dehydrated and encouraged me to drink fluids and eat something. I knew it was more than that. My family and I decided that someone needed to take me to the doctor or the ER. While I was grabbing my purse and cell phone, I became so nauseated and dizzy that I almost fell over. At this point, we called 9-1-1.

I lay on the bench in my hallway, waiting for the ambulance to arrive, while the doctor in me still tried to self-diagnose the situation. It has to be poisoning, I thought. I must have touched some household chemical underneath the sink, and then accidentally ingested it somehow. Soon, I began to slur my speech; then, as my right arm and the right side of my face went numb, I sadly congratulated myself on finally realizing the correct diagnosis. Stroke.

Failure to Communicate

In the ambulance and ER, my speech improved as they gave me oxygen. The slurring was minimal; however, I could not form the right words. I tried to explain the initial dark spot in my vision

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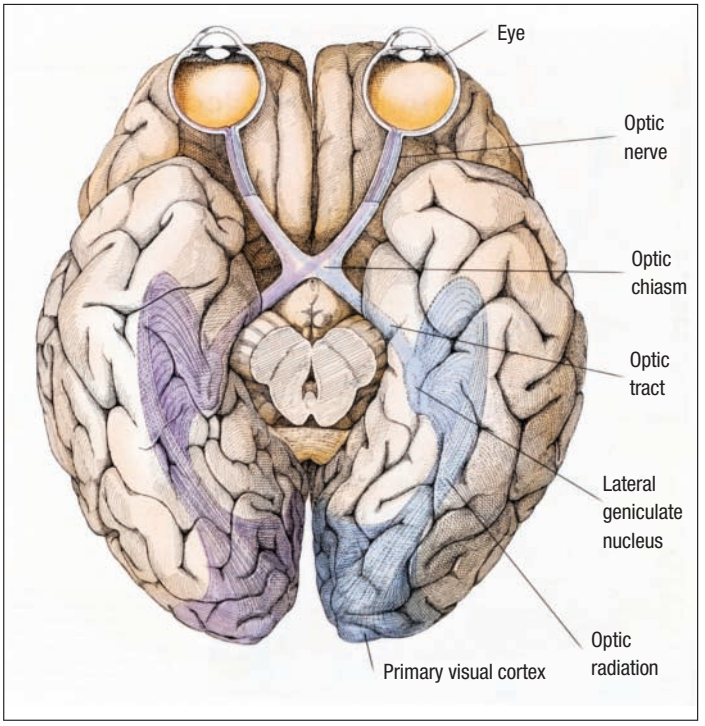
to the doctors , but I could not say the word "vision"—I kept saying "version." In my mind, I was cognitively all there. I was stunned and astonished to hear the sound of my own voice, disembodied from me, saying the wrong word. I repeated the word several times, but it came out wrong every time. I couldn't believe what I was hearing from my own mouth!

I thought maybe I could communicate with them better by writing so I motioned for the nurse to give me paper and a pen, thinking I would give them a hand-written account of what had happened. But each and every time I went to say the words "hand written," it came out as "hard," and she couldn't understand what I was requesting. I was flabbergasted. I felt trapped in my own mind, unable to communicate. I saw the looks on the faces of the nurses and doctors and knew that they had given up on me being able to tell them what had happened. It was a horrible feeling. It has made me more sympathetic to patients in my chair who have a tough time communicating with me as their doctor, and it has given me more patience in listening to what it is they're trying to say.

Over the next few hours in the ER, I must have had every test in the book—including blood work, chest X-rays, a CT scan, carotid Doppler ultrasounds, a magnetic resonance angiogram and an MRI of my head, neurological testing and an electrocardiogram. Absolutely everything came back normal. The doctors told me the good news was that I was definitely a very healthy young woman; the bad news was that I had experienced a TIA.



A TIA often affects the anatomy of the visual pathway, frequently manifesting as severe monocular vision loss or blindness that occurs suddenly and resolves in less than five minutes.[5]

With an ischemic stroke, a blood clot blocks an artery in the brain and stays there. With a hemorrhagic stroke, a blood vessel bursts in the brain. But with a TIA or mini-stroke, a blood clot blocks an artery in the brain temporarily and then moves on.

Because my cholesterol levels were normal and I had no blood clotting disorders, they believed a positional blood clot had caused the TIA. They suspected the blood clot had formed in my leg because it wasn't getting proper circulation due to the way I was sitting on the floor while I was reading the book. They imagined the blood clot must have been smaller than the head of a pin, and that it traveled to my brain, where it stayed for the next several hours. Eventually, it dislodged itself and went on its way.

The doctors asked me questions about my heart health, and if I had been born premature. I was delivered at full term, and although I had a family history of heart disease, I never experienced any heart problems or murmurs myself. They told me that we all get tiny clots and debris in our blood at times, and that usually our lungs filter them out. But, sometimes, an otherwise healthy person can suffer a TIA because a tiny blood clot goes straight to the brain, bypassing the normal circulation route through the heart and filtration through the lungs.

The Culprit

In a healthy heart, normal blood flow moves from the body to the heart, through the lungs back to heart, and then finally gets redistributed through the body. After circulating through the body, deoxygenated blood returns to the heart and enters the right atrium. Then, it goes through the tricuspid valve to the right ventricle, and exits the heart from the pulmonary valve.

Next, the pulmonary arteries carry the blood to the lungs to get fresh oxygen. The re-oxygenated blood travels back to the heart via the pulmonary veins and enters the

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Reference: 1. Data on file. Johnson & Johnson Vision Care, Inc. 2009.

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left atrium; then, it passes through the mitral valve to the left ventricle. The left ventricle pumps the oxygenated blood to the aorta and other arteries, where it gets redistributed to the body and brain.[1]

A patent foramen ovale (PFO) is a hole in the atrial septum, the wall that divides the left and right atria (upper chambers of the heart). Everyone has this hole while in the womb, but usually the hole closes shortly after birth. However, in 20% of people, it does not.[2] Tiny blood clots formed in the body can use this congenital heart defect in the atrial-septal wall as a door to return to the heart and go straight to the brain, instead of going through the normal filtration and re-oxygenation system of the lungs. Preemies are sometimes born with PFOs, which is why neonatal intensive care units screen for them, but a full-term baby (the average person) never gets screened for a PFO.

A transesophageal echocardiogram (TEE) is used to detect a PFO in adults, using a transducer (sort of like a microphone) to send sound waves through the heart. These waves bounce off different structures in the heart, and help to assess the heart's function and check for structural abnormalities. The transducer is fed down the esophagus, while the patient is under general anesthesia. Going through the esophagus yields a clearer image of the heart from its back side because the sound waves do not have to travel through the skin, bones and muscle like they would if the transducer were placed over the heart on the outside of the chest.

When all of my other tests came back absolutely normal, the doctors recommended a TEE, so I fasted and underwent the procedure the next morning. Lo and behold, there it was—I indeed had a PFO.

Signs and Symptoms[4]

It's important to know and watch out for the signs and symptoms of a stroke. Seek medical attention immediately if you have any of the following:

- SUDDEN numbness or weakness of face, arm or leg—especially on one side of the body.
- SUDDEN confusion, trouble speaking or understanding.
- SUDDEN trouble seeing in one or both eyes.
- SUDDEN trouble walking, dizziness, loss of balance or coordination.
- SUDDEN severe headache with no known cause.

Once a PFO is diagnosed in a patient who has had a TIA, the doctor may prescribe blood-thinners if they feel that line of treatment may help to prevent another clot from forming and causing a repeat TIA or stroke.[3] Another option is to have an umbrella-like device implanted, which closes the holes permanently once it's positioned in the atrial-septal wall and opened. It's not open-heart surgery; the entire procedure is done through a catheter fed through a vein in the leg. Trials are still ongoing to determine whether anti-coagulant therapy and PFO closure surgery are equally as effective when it comes to reducing the likelihood of a second TIA or stroke. The decision ultimately lies in the hands of the doctor and the patient.

Closing the Door

Forty-two days after my TIA, I had PFO closure heart surgery. I find comfort in the fact that this pathway is now closed, and I am hoping to live the rest of my life stroke-free. I am extremely lucky that I haven't had any residual effects from the mini-stroke and that I survived. It is impossible to know if what you are experiencing is a TIA, ischemic stroke or hemorrhagic stroke, and proper medical intervention is absolutely necessary to protect your health and your life. (*See "Signs and Symptoms," left.*)

To this day, I still shake my head at the fact that I misdiagnosed myself! That little black spot in my vision. Although I disregarded it at first, at least I had enough sense to be on high alert for any other peculiar signs or symptoms that popped up. The doctors say it was good that I acted fast and did not ignore my other symptoms. I got oxygen quickly from the ambulance because of calling 9-1-1 right away—and, in a stroke, that matters.

Having a TIA is a potential warning sign of a future stroke or some serious underlying issues. That is why I feel it is so important for us as optometrists to be on the lookout for weird symptoms and stories from our patients, even in those who are young and seem completely healthy. We are trained that "when you hear hoof beats, think horses, not zebras," but as a zebra, I can tell you from personal experience, sometimes the most likely diagnosis is not always the correct one. ■

Dr. Murphy practices full-scope optometry in Holbrook, N.Y.

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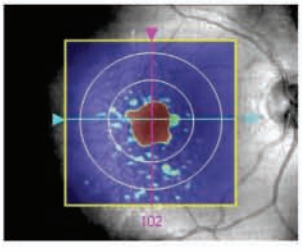

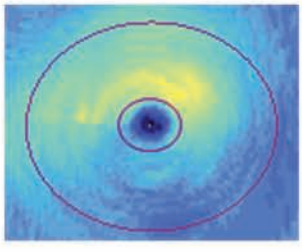

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Smarten Up Your EyePhone

Here are 16 eye care apps to supercharge your smart phone or tablet into an optometric dynamo. **By Stefania Paniccia, M.S.**

People these days are inseparable from their smart phones and tablets. Optometrists and other health professionals aren't immune to the infectious appeal of these devices; those of us who've invested in these hand-held wonders understand their efficiency, capacity and usefulness. They've transformed how we communicate and share information in our everyday, hectic lives.

The familiar phrase, "There's an app for that!" also applies to eye care, with an abundance of ingenious eye-related goodies available for our favorite gadgets. But, there are more than 500,000 apps available in the iTunes marketplace alone. Sorting out what's useful is not only time consuming, it's also overwhelming, to say the least. With all of these choices, where do you begin optimizing your device into an optometric powerhouse?

Fortunately, as an optometry student, I have loads of free time! (*Sarcasm alert.*) So, I've done the legwork for you. Here's a list of more than a dozen apps that I use and have found incredibly helpful with clinical rounds and patient encounters. Grab your smart device and get ready.

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ICD 9 (With - 2012 Codes)
T V N, $0.99

Highly rated and inexpensive compared to other apps with similar content. This app has complete offline access to more than 17,500 ICD-9 codes with free updates.

Compatible with iPad, iPhone and iPod touch.

Optics Clinical Calculator
Evan Schoenberg, $4.99

A vital tool for prescribing lenses, this app includes streamlined, intuitive access to optical calculators. Base curves, obliquely crossed cylinders, slab-off and much more are made easy with this efficient app.

Compatible with iPad, iPhone and iPod touch.

Medical Lab Tests
Medicon Apps, $2.99

Interpreting lab results and remembering normal values can often be difficult. Can you recall the normal value of a hematocrit or

the reference value for amylase? This application will help you. Included are the most common laboratory tests and their interpretation.

Compatible with iPad, iPhone and iPod touch.

Neurology Suite
Börm Bruckmeier Publishing, free

This is an excellent neurology reference for clinicians. Specifically, it's a collection of applications containing valuable, quick-reference neuro guides.

This app is actually the "lite" version; for an in-app purchase of $3.99, you can expand it with Neurology i-pocketcards. These are concise neuro-related tables, containing information about ocular movement disorders, cranial nerves, ocular muscle innervations and various tests for nerve function.

Compatible with iPad, iPhone and iPod touch.

iMedsXL - The Medication Reference
FDAble LLC, $3.99

This app contains full prescribing information for more than 7,300 FDA-approved medications. The advantage to this app is its offline access search via drug name or drug class. It also includes contraindications.

Compatible with iPad.

Eponyms
Pascal Pfiffner, $1.99

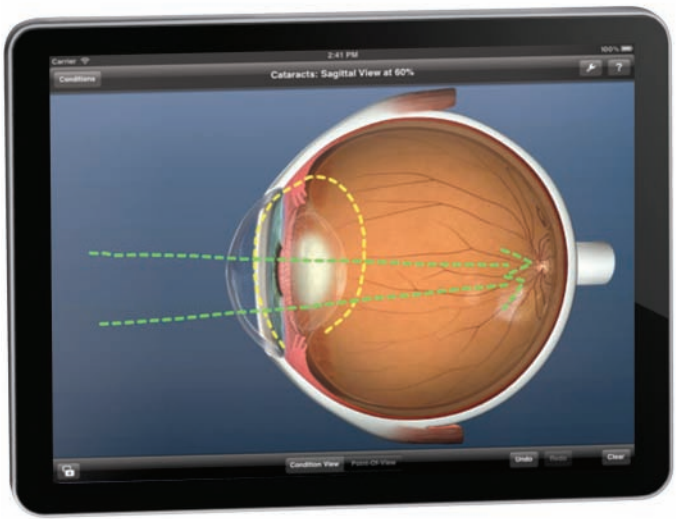
What exactly is an "eponym"? We use them all the time. According to Merriam-Webster, it's the name of a person or thing, real or fictitious, after which a particular place, tribe, discovery or other item is named. Usher's syndrome and Addison's disease are examples of eponyms. This app gives a short description of more than 1,700 common and obscure medical eponyms.

Compatible with iPad, iPhone, iPod touch and Android.

Ophthalmology i-pocketcards
Börm Bruckmeier Publishing, $4.99

Another quick reference guide for the eye care clinician, this app includes quick "pocketcards" on eye anatomy, management of refractive errors, images to test for color blindness, ocular complications of diabetes, and much more.

Compatible with iPad, iPhone or iPod touch.



The LUMA Vision Simulator app, by Eyemaginations, allows you to perform visual patient education right from your iPad.

LUMA Vision Simulator
Eyemaginations Inc., free

Explaining eye pathology to a patient can be challenging. The LUMA Vision Simulator alleviates some of that difficulty by providing visuals to explain eight common diseases of the eye. Included are dry eye, myopia, diabetic retinopathy, age-related macular degeneration and other commonly encountered pathologies. An on-screen drawing tool allows you to annotate directly on the image for a more detailed approach.

Compatible with the iPad.

EyeDock
Todd M Zarwell OD, free

Created by optometrist Todd M. Zarwell, this is a companion app to eyedock.com, a website for eye care professionals. The EyeDock application contains a regularly updated database for contact lens fitting and ophthalmic medications as well as keratometric conversions. Just added: a gas permeable lens database of more than 1,200 lenses, and an interactive refraction tutorial. Although the app is free, an EyeDock membership is required to use it, obtained through eyedock.com.

Compatible with iPad, iPhone or iPod touch.

CL Calcs
Todd M Zarwell OD, $7.99

This is a "lite" version of the EyeDock app without the need for an EyeDock membership. It provides contact lens calculators and

much more. Included is a vertexing tool for spectacles, post-surgical keratometry conversions and contact lens design suggestions, all in the palm of your hand. Also, this is an excellent app to begin designing an RGP lens, as well as for designing other contact lenses.

Compatible with iPad, iPhone, and iPod touch.

Eye Handbook
Cloud Nine Development, free

With a pharmacopoeia, equipment reference, testing, coding and media center for patient education, this may become your most frequently used application. There are also excellent in-app purchases to add, such as information for multifocal IOLs, punctal plugs and uveitis. In short, this is a versatile and comprehensive addition to your O.D. smart device.

Compatible with iPad, iPhone, iPod touch and Android.

Take retinal images using the iExaminer app, the camera on your iPhone and mounting hardware.

ODwire.org
End of Time Studios, free

The largest social network for eye care professionals is now at your fingertips. ODwire.org is open to all optometrists, ophthalmologists, licensed opticians and students. Included in this forum are clinical and practice management tips, an online marketplace, and informative web seminars.

Compatible with iPad, iPhone and iPod touch.

Epocrates
Epocrates Inc., free

This application is currently the number one mobile drug reference among physicians in the United States. It offers quick access to reliable drug, disease and diagnostic information when you need it. Included is free clinical information on thousands of prescription and generic drugs, a pill identifier, drug interaction information and current medical news. An in-app purchase of a premium package adds ICD-9 codes, a medical dictionary, treatment guidelines, and more. You'll need an account with Epocrates to use this app, which can be created at www.epocrates.com.

Compatible with iPad, iPhone, iPod touch and Android.

Diagnosaurus DDx
Unbound Medicine, $0.99

Do you need a differential diagnosis for that red eye or atypical conjunctivitis? Diagnosaurus DDx helps health care professionals do so with speed and confidence at the point of care. Quickly search more than 1,000 diagnoses by organ system, symptom or disease. Specific searches can be bookmarked for fast retrieval in the future.

Compatible with iPad, iPhone, iPod touch and all Windows phone devices.

iExaminer
Intuitive Medical Technologies, free

Optimized for use with iExaminer hardware (available at www.iExam.com), this is the first and only app that allows imaging of the retina using the camera on your iPhone. iExaminer adapts the iPhone 4 to the Welch Allyn PanOptic for high-resolution fundus photos. It can also record simultaneous video. It's a fundus camera that's as portable and as easy to use as your iPhone.

Compatible with iPad, iPhone, and iPod touch. ■

Ms. Paniccia is a third-year student at InterAmerican University of Puerto Rico School of Optometry. She has no financial interests in any of the applications mentioned in this article.

Disclaimer: The opinions expressed in this article are those of the author and do not necessarily represent those of Apple Inc., Google Inc., or their affiliates. Users of these applications should not rely solely on them in diagnosing or treating a condition.

A shorter version of this article appeared previously on www.optometrystudents.com.

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Reference: 1. Alcon data on file, 2011.

 1/12 DAL12017JAD

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PEER • REVIEWED • RRA • ARTICLE

How (and Why) to Make Autologous Serum

If conventional therapy isn't up to scratch for severe dry eye, consider autologous serum. It may be easier and more effective than you think.

By Richard Mangan, O.D., and Shana Lehman, C.O.A

An 81-year-old white male was referred to our dry eye clinic for a consultation on severe keratitis sicca secondary to Sjögren's syndrome. His ocular history was remarkable for chronic "grittiness, scratchiness and burning" in both eyes that was recalcitrant to conventional therapy.

His current treatment regimen includes Lotemax (loteprednol etabonate 0.5%, Bausch + Lomb) b.i.d., Restasis (cyclosporine A 0.05%, Allergan) b.i.d., punctal occlusion of the lower lids, Systane Preservative-Free (Alcon) artificial tears every two to four hours while awake, and GenTeal Gel (Novartis) at bedtime, all used bilaterally. Additionally, the patient wears wraparound glasses when outdoors, and uses a cool-air mist humidifier in the living room and bedroom. His past ocular history also includes pseudophakia O.U.

His medical history is significant for high cholesterol, hypertension, primary Sjögren's syndrome and acid reflux. Systemic medications include omeprazole, Zetia (ezetimibe, Merck), and low-dose (81mg) aspirin, all dosed once daily.

Pertinent exam findings included:

- Best-corrected visual acuity: 20/25- O.D., 20/25- O.S.
- Mild conjunctival injection O.U.
- Corneal filaments O.U.
- Diffuse superficial punctate keratopathy O.U.
- 3+ lissamine green staining O.U.
- Well-positioned Freeman style silicone punctal

Autologous serum eye drops (ASEDs) are not conventional therapy, but they can certainly be effective therapy for severe dry eye patients, such as those with Sjögren's syndrome.

Join us for a Webinar

ALLERGIC CONJUNCTIVITIS:

A Growing Patient Problem and Treatment Opportunity

SPEAKERS

Richard Lindstrom, MD
Paul Karpecki, OD
Edward Holland, MD
Stephen S. Lane, MD

TOPICS

- The importance of differential diagnosis of allergic conjunctivitis
- Prevalence and causes of allergic conjunctivitis
- Treatment modalities for itching associated with allergic conjunctivitis
- Mechanisms of action

SCHEDULE

Day	Date	Time
Thursday	March 8	9 pm EST/6 pm PST
Tuesday	March 13	8 pm EST/5 pm PST
Wednesday	March 14	7 pm EST/4 pm PST
Thursday	March 15	8 pm EST/5 pm PST
Tuesday	March 20	7 pm EST/4 pm PST
Wednesday	March 21	9 pm EST/6 pm PST
Tuesday	April 3	9 pm EST/6 pm PST
Wednesday	April 4	8 pm EST/5 pm PST
Thursday	April 5	7 pm EST/4 pm PST
Wednesday	April 11	9 pm EST/6 pm PST

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Dry Eye Severity Grading Scheme

Dry Eye Severity Level	1	2	3	4*
Discomfort, severity and frequency	Mild and/or episodic; occurs under environmental stress	Moderate episodic or chronic stress or no stress	Severe, frequent or constant without stress	Severe and/or disabling and constant
Visual symptoms	None or episodic mild fatigue	Annoying and/or activity limiting episodic	Annoying, chronic and/or constant, limiting activity	Constant and/or possibly disabling
Conjunctival injection	None to mild	None to mild	+/-	+/++
Conjunctival staining	None to mild	Variable	Moderate to marked	Marked
Corneal staining (severity/location)	None to mild	Variable	Marked central	Severe punctate erosions
Corneal/tear signs	None to mild	Mild debris, ê meniscus	Filamentary keratitis, mucus clumping, é tear debris	Filamentary keratitis, mucus clumping, é tear debris, ulceration
Lid/meibomian glands	Meibomian gland disease (MGD) variably present	MGD variably present	Frequent	Trichiasis, keratinization, symblepharon
Tear film break-up time	Variable	≤ 10 seconds	≤ 5 seconds	Immediate
Schirmer score (per five min.)	Variable	≤ 10mm	≤ 5mm	≤ 2mm

* Must have signs *and* symptoms.

Source: Behrens A, Doyle JJ, Stern L,et al; Dysfunctional tear syndrome study group. Dysfunctional tear syndrome: a Delphi approach to treatment recommendations. Cornea. 2006 Sep;25(8):900-7.

plugs O.U. (lower puncta)

• Intermittent incomplete closure on blink O.U. showing mild sclera

• Adequate lid apposition O.U.

• Schirmer tear test without anesthesia: <1mm in each eye

• Blink rate: frequent (approximately every three to four seconds)

Our clinical impression was that he had severe keratitis sicca (DEWS criteria stage 3) O.U.

Given his ocular history and current clinical findings, we discussed autologous serum eye drops (ASEDs) as a treatment option. We reviewed the risks, benefits and alternatives of autologous serum, as well as the fees involved. Upon consideration, the patient agreed to a three-month trial of ASEDs.

Accordingly, we prescribed 20% autologous serum eye drops q2h while awake O.U. We instructed him to continue Lotemax b.i.d. O.U., and GenTeal Gel at bedtime O.U., but to discontinue Restasis and Systane.

We explained that he would receive approximately 50 to 55 bottles (3ml size with a 2ml fill) of preservative-free ASEDs. We told him to store unopened bottles in the household freezer for no longer than three months. Opened bottles are to be stored in the refrigerator but must be used within 48 hours or be discarded. We told him to notify our office immediately if he notices any adverse side effects. We asked him to bring all used and partially used bottles back to our office for proper disposal.

At his one-month follow-up visit, he reported a significant improvement in his symptoms. He indicated that the burning and irritation had decreased greatly; he noted that he "couldn't remember the last time his eyes felt this good."

Clinically, he showed a 30% improvement in vital dye staining, and subtle improvement in tear film break-up times O.U. There was complete resolution of his corneal filaments, and visual acuity improved by one line of vision. We asked him to continue ASEDs every two hours while awake, and to use Lotemax on an as-needed basis up to twice per day.

At his three-month follow-up visit, the patient reported a mild improvement in his vision from the last visit, with only a few instances of burning and irritation that warranted the use of Lotemax. Slit-lamp biomicroscopy showed inferior staining of the cornea with sodium fluorescein, and mild

SWITCH TO THE POWER OF BEPREVE

For the treatment of itching associated with allergic conjunctivitis

Turn off itch—turn on comfort.

Discover the power to turn off ocular itching associated with allergic conjunctivitis–even for severe patients.

BEPREVE (bepotastine besilate ophthalmic solution) is indicated for the treatment of itching associated with allergic conjunctivitis. BEPREVE is for topical ophthalmic use only. To minimize risk of contamination, do not touch the dropper tip to any surface. Keep the bottle closed when not in use. BEPREVE should not be used to treat contact lens-related irritation. Remove contact lenses prior to instillation of BEPREVE. The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions occurring in 2%-5% of patients were eye irritation, headache, and nasopharyngitis.

Prescribe the Power.™

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www.istavision.com

BEPREVE®
(bepotastine besilate ophthalmic solution) 1.5%

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BEPREVE (bepotastine besilate ophthalmic solution) 1.5% safely and effectively.

See full prescribing information for BEPREVE.

BEPREVE
(bepotastine besilate ophthalmic solution) 1.5%

Initial U.S. Approval: 2009

----------INDICATIONS AND USAGE----------

BEPREVE is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with allergic conjunctivitis. (1)

----------DOSAGE AND ADMINISTRATION----------

Instill one drop into the affected eye(s) twice a day (BID). (2)

----------DOSAGE FORMS AND STRENGTHS----------

Solution containing bepotastine besilate, 1.5%. (3)

----------WARNINGS AND PRECAUTIONS----------

- To minimize the risk of contamination, do not touch dropper tip to any surface. Keep bottle tightly closed when not in use. (5.1)
- BEPREVE should not be used to treat contact lens-related irritation. (5.2)
- Remove contact lenses prior to instillation of BEPREVE. (5.2)

----------ADVERSE REACTIONS----------

The most common adverse reaction occurring in approximately 25% of patients was a mild taste following instillation. Other adverse reactions which occurred in 2-5% of subjects were eye irritation, headache, and nasopharyngitis. (6)

To report SUSPECTED ADVERSE REACTIONS, contact ISTA Pharmaceuticals, Inc. at 1-877-788-2020, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 01/2010

FULL PRESCRIBING INFORMATION:
CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is a histamine H_1 receptor antagonist indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis.

2 DOSAGE AND ADMINISTRATION

Instill one drop of BEPREVE into the affected eye(s) twice a day (BID).

3 DOSAGE FORMS AND STRENGTHS

Topical ophthalmic solution containing bepotastine besilate 1.5%.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Contamination of Tip and Solution

To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

5.2 Contact Lens Use

Patients should be advised not to wear a contact lens if their eye is red. BEPREVE should not be used to treat contact lens-related irritation.

BEPREVE should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of BEPREVE. The preservative in BEPREVE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of BEPREVE.

5.3 Topical Ophthalmic Use Only

BEPREVE is for topical ophthalmic use only.

6 ADVERSE REACTIONS

The most common reported adverse reaction occurring in approximately 25% of subjects was a mild taste following instillation. Other adverse reactions occurring in 2-5% of subjects were eye irritation, headache, and nasopharyngitis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Teratogenicity studies have been performed in animals. Bepotastine besilate was not found to be teratogenic in rats during organogenesis and fetal development at oral doses up to 200 mg/kg/day (representing a systemic concentration approximately 3,300 times that anticipated for topical ocular use in humans), but did show some potential for causing skeletal abnormalities at 1,000 mg/kg/day. There were no teratogenic effects seen in rabbits at oral doses up to 500 mg/kg/day given during organogenesis and fetal development (>13,000 times the dose in humans on a mg/kg basis). Evidence of infertility was seen in rats given oral bepotastine besilate 1,000 mg/kg/day; however, no evidence of infertility was observed in rats given 200 mg/kg/day (approximately 3,300 times the topical ocular use in humans). The concentration of radiolabeled bepotastine besilate was similar in fetal liver and maternal blood plasma following a single 3 mg/kg oral dose. The concentration in other fetal tissues was one-third to one-tenth the concentration in maternal blood plasma.

An increase in stillborns and decreased growth and development were observed in pups born from rats given oral doses of 1,000 mg/kg/day during perinatal and lactation periods. There were no observed effects in rats treated with 100 mg/kg/day.

There are no adequate and well-controlled studies of bepotastine besilate in pregnant women. Because animal reproduction studies are not always predictive of human response, BEPREVE (bepotastine besilate ophthalmic solution) 1.5% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

Following a single 3 mg/kg oral dose of radiolabeled bepotastine besilate to nursing rats 11 days after delivery, the maximum concentration of radioactivity in milk was 0.40 µg-eq/mL 1 hour after administration; at 48 hours after administration the concentration was below detection limits. The milk concentration was higher than the maternal blood plasma concentration at each time of measurement.

It is not known if bepotastine besilate is excreted in human milk. Caution should be exercised when BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is administered to a nursing woman.

8.4 Pediatric Use

Safety and efficacy of BEPREVE (bepotastine besilate ophthalmic solution) 1.5% have not been established in pediatric patients under 2 years of age. Efficacy in pediatric patients under 10 years of age was extrapolated from clinical trials conducted in pediatric patients greater than 10 years of age and from adults.

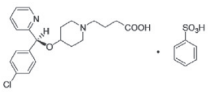
8.5 Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

11 DESCRIPTION

BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is a sterile, topically administered drug for ophthalmic use. Each mL of BEPREVE contains 15 mg bepotastine besilate.

Bepotastine besilate is designated chemically as (+) -4-[[(S)-p-chloro-alpha -2-pyridylbenzyl]oxy]-1-piperidine butyric acid monobenzenesulfonate. The chemical structure for bepotastine besilate is:



Bepotastine besilate is a white or pale yellowish crystalline powder. The molecular weight of bepotastine besilate is 547.06 daltons. BEPREVE ophthalmic solution is supplied as a sterile, aqueous 1.5% solution, with a pH of 6.8.

The osmolality of BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is approximately 290 mOsm/kg.

Each mL of BEPREVE (bepotastine besilate ophthalmic solution) 1.5% contains:
Active:
Bepotastine besilate 15 mg (equivalent to 10.7 mg bepotastine)
Preservative: benzalkonium chloride 0.005%
Inactives: monobasic sodium phosphate dihydrate, sodium chloride, sodium hydroxide to adjust pH, and water for injection, USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bepotastine is a topically active, direct H_1-receptor antagonist and an inhibitor of the release of histamine from mast cells.

12.3 Pharmacokinetics

Absorption: The extent of systemic exposure to bepotastine following topical ophthalmic administration of bepotastine besilate 1% and 1.5% ophthalmic solutions was evaluated in 12 healthy adults. Following one drop of 1% or 1.5% bepotastine besilate ophthalmic solution to both eyes four times daily (QID) for seven days, bepotastine plasma concentrations peaked at approximately one to two hours post-instillation. Maximum plasma concentration for the 1% and 1.5% strengths were 5.1 ± 2.5 ng/mL and 7.3 ± 1.9 ng/mL, respectively. Plasma concentration at 24 hours post-instillation were below the quantifiable limit (2 ng/mL) in 11/12 subjects in the two dose groups.

Distribution: The extent of protein binding of bepotastine is approximately 55% and independent of bepotastine concentration.

Metabolism: *In vitro* metabolism studies with human liver microsomes demonstrated that bepotastine is minimally metabolized by CYP450 isozymes.

In vitro studies demonstrated that bepotastine besilate does not inhibit the metabolism of various cytochrome P450 substrate via inhibition of CYP3A4, CYP2C9, and CYP2C19. The effect of bepotastine besilate on the metabolism of substrates of CYP1A2, CYP2C8, CYP2D6 was not studied. Bepotastine besilate has a low potential for drug interaction via inhibition of CYP3A4, CYP2C9, and CYP2C19.

Excretion: The main route of elimination of bepotastine besilate is urinary excretion (with approximately 75-90% excreted unchanged in urine).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term dietary studies in mice and rats were conducted to evaluate the carcinogenic potential of bepotastine besilate. Bepotastine besilate did not significantly induce neoplasms in mice receiving a nominal dose of up to 200 mg/kg/day for 21 months or rats receiving a nominal dose of up to 97 mg/kg/day for 24 months. These dose levels represent systemic exposures approximating 350 and 200 times that achieved with human topical ocular use.

The no observable adverse effect levels for bepotastine besilate based on nominal dose levels in carcinogenicity tests were 18.7 to 19.9 mg/kg/day in mice and 9.6 to 9.8 mg/kg/day in rats (representing exposure margins of approximately 60 and 20 times the systemic exposure anticipated for topical ocular use in humans).

There was no evidence of genotoxicity in the Ames test, in CHO cells (chromosome aberrations), in mouse hepatocytes (unscheduled DNA synthesis), or in the mouse micronucleus test.

When oral bepotastine was administered to male and female rats at doses up to 1,000 mg/kg/day, there was a slight reduction in fertility index and surviving fetuses. Infertility was not seen in rats given 200 mg/kg/day oral bepotastine besilate (approximately 3,300 times the systemic concentration anticipated for topical ocular use in humans).

14 CLINICAL STUDIES

Clinical efficacy was evaluated in 2 conjunctival allergen challenge (CAC) studies (237 patients). BEPREVE (bepotastine besilate ophthalmic solution) 1.5% was more effective than its vehicle for relieving ocular itching induced by an ocular allergen challenge, both at a CAC 15 minutes post-dosing and a CAC 8 hours post dosing of BEPREVE.

The safety of BEPREVE was evaluated in a randomized clinical study of 861 subjects over a period of 6 weeks.

16 HOW SUPPLIED/STORAGE AND HANDLING

BEPREVE (bepotastine besilate ophthalmic solution) 1.5% is supplied in a white low density polyethylene plastic squeeze bottle with a white controlled dropper tip and a white polypropylene cap in the following size:

5 mL (NDC 67425-007-50)
10 mL (NDC 67425-007-75)

STORAGE
Store at 15° – 25°C (59° – 77°F).

17 PATIENT COUNSELING INFORMATION

17.1 Topical Ophthalmic Use Only

For topical ophthalmic administration only.

17.2 Sterility of Dropper Tip

Patients should be advised to not touch dropper tip to any surface, as this may contaminate the contents.

17.3 Concomitant Use of Contact Lenses

Patients should be advised not to wear a contact lens if their eye is red. Patients should be advised that BEPREVE should not be used to treat contact lens-related irritation.

Patients should also be advised to remove contact lenses prior to instillation of BEPREVE. The preservative in BEPREVE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of BEPREVE.

Rx only

Manufactured for: ISTA Pharmaceuticals®, Inc.
Irvine, CA 92618

By: Bausch & Lomb Incorporated
Tampa, FL 33637

Under license from:
Senju Pharmaceutical Co., Ltd.
Osaka, Japan 541-004

BRV859-7/10

staining of the conjunctiva with lissamine green. The tear prism was expectedly scant, but his blink rate had improved to approximately every six seconds.

Given the positive clinical findings and improved patient symptoms—and knowing that insurance does not cover this form of therapy—I suggested that we could try a three-month on/three-month off protocol, and see if he could maintain his comfort level with preservative-free tears during the off months.

But, with the improvement in his symptoms, the patient was adamant about continuing the ASED therapy. I agreed to prescribe another three-month supply at q2h dosing, as long as he agreed to discontinue the use of any bottles that are refrigerated for 48 hours or longer, and to bring the used and unused bottles at each subsequent follow-up visit.

Sjögren's and DEWS

Sjögren's syndrome (SS) is a systemic autoimmune disease in which immune cells attack and destroy host exocrine glands that produce tears and saliva.[1] SS has an estimated prevalence of 0.05% to 4.8%, or about 1.3 million Americans.[2] It occurs much more often in women than men, at a ratio of 9:1.[2] The peak incidence is between the fourth and fifth decades of life, but it can affect all age groups and ethnic groups.

With respect to ocular involvement, the lacrimal glands are infiltrated by activated T-cell lymphocytes resulting in the release of inflammatory mediators (cytokines) into tears, promoting inflammation of the ocular surface. This inflammation adversely affects the neurosensory feedback loop vital to maintaining tear film homeostasis, eventually leading to cellular apoptosis. Patients with ocular surface disease related to Sjögren's syndrome often show a lack of both basal and reflex tearing as well as vital dye staining that is more severe than in non-Sjögren's dry eye patients.[3,4]

Based on diagnostic and treatment guidelines for stages of dry eye disease, published in the International DEWS (Dry Eye Workshop) Report, our patient presented with signs and symptoms consistent with dry eye severity level three.[5] (*See "Dry Eye Severity Grading Scheme," page 44.*) One of the treatment strategies recognized by DEWS for stage three dry eye patients is autologous serum eye drops. (*See "Treatment Recommendations by Severity Level," right.*)

Autologous Serum

Loss of tear production can have severe visual consequences. Our natural tears are made up of key components not found in artificial tear products, such as epidermal growth factor (EGF), fibronectin and vitamin A, which support the proliferation, maturation, migration and differentiation of corneal and conjunctival epithelia.[6] We also know that serum contains IgG, lysozymes and complement, which have bacteriostatic properties. If these factors are low or missing, there is increased risk of persistent epithelial defects, blurred vision, infection and scarring.

The concept of using serum as an eye drop is based on the understanding that there are biochemical similarities between an individual's serum and natural tears.[7] There have been a number of studies demonstrating the wound healing effects of ASEDs.[8,9] But it has been the work of rheumatologist Robert Fox, M.D., Ph.D., at Scripps Memorial Hospital in California, and ophthalmologist Kazuo Tsubota, M.D., of Keio University School of Medicine in Tokyo, who have driven renewed interest in ASEDs for severe dry eye disease.

Dr. Fox and his colleagues were among the first to report improve-

Treatment Recommendations by Severity Level

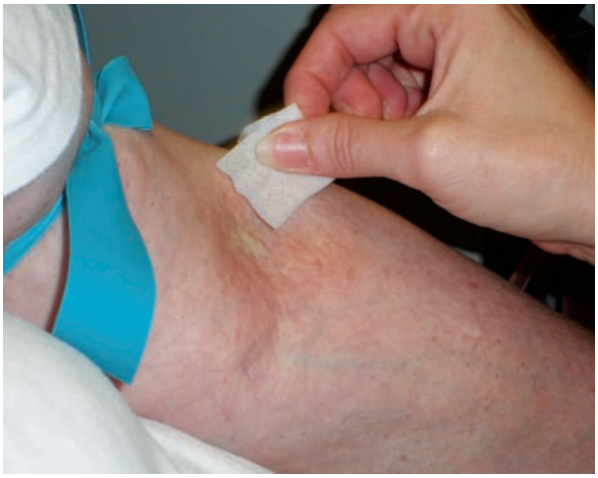
Level 1
- Education
- Environmental/dietary modifications
- Elimination of offending systemic medications
- Artificial tear substitutes, gels/ointments
- Eyelid therapy

Level 2
If Level 1 treatments are inadequate, add:
- Anti-inflammatories
- Tetracyclines (for meibomianitis, rosacea)
- Punctal plugs
- Secretogogues
- Moisture chamber spectacles

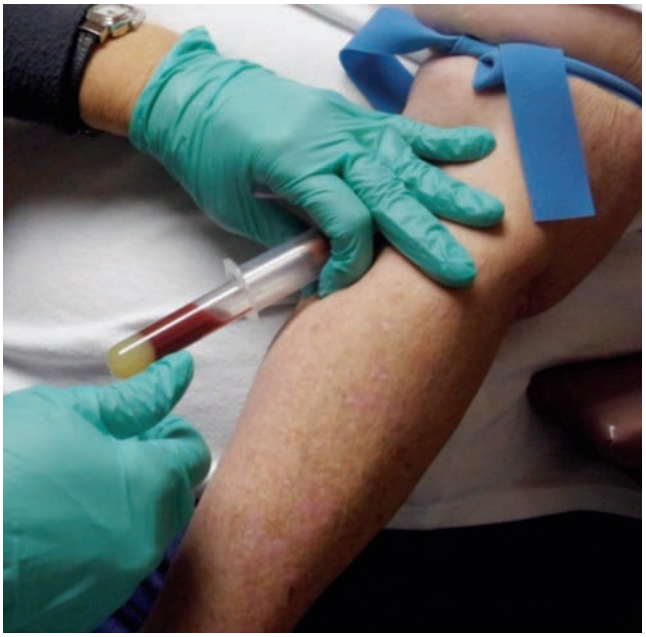
Level 3
If Level 2 treatments are inadequate, add:
- Serum
- Contact lenses
- Permanent punctal occlusion

Level 4
If Level 3 treatments are inadequate, add:
- Systemic anti-inflammatory agents
- Surgery (lid surgery, tarsorrhaphy; mucus membrane, salivary gland, amniotic membrane transplantation)

Source: Wilson SE, Stulting RD. Agreement of physician treatment practices with the international task force guidelines for diagnosis and treatment of dry eye disease. Cornea. 2007 Apr;26(3):284-9.



Once a donor health questionnaire and informed consent are signed, the venipuncture site is prepped with either alcohol or povidone iodine swab.



Using an 18-gauge needle, approximately 40ml of blood is collected in six 8.5cc blood tubes.

ment in clinical signs and symptoms in *all* patients treated (n=15) with 50% ASEDs for moderate to severe keratitis sicca, during a mean follow-up period of 10 months.[10] Eight of the 15 patients carried the diagnosis of Sjögren's syndrome.

Fifteen years later, Dr. Tsubota's group studied the impact of 20% autologous serum on fluorescein and rose bengal staining, tear film break-up time and symptomology based on subjective face scoring in 12 patients diagnosed with Sjögren's syndrome. Their analysis showed that within two to four weeks of treatment, there was clinically significant improvement in *all* objective clinical parameters as well as symptoms.[11]

How to Formulate ASEDs

Once a donor health questionnaire and informed consent are signed, the venipuncture site is prepped with either alcohol or povidone iodine swab. Using an 18-gauge needle, approximately 40ml of blood is collected into six 8.5cc blood tubes.

The collected blood is set aside to clot for two hours at room temperature. Then the blood is centrifuged at 5,600 rpm for 10 minutes. The serum is filtered through a 25mm polyethersulfone disc filter before mixing with saline. Filtration is performed to remove fibrin strands, which are believed to lessen the effect of ASEDs. Each 8.5cc tube of blood yields approximately 4cc of serum (24cc total).

There are no large-scale, double-blind, placebo-controlled studies that describe an optimal concentration or optimal dosing schedule for this treatment. So, in our practice, we opt for a 20% solution based on the concentration level of transforming growth factor B1 (TGF-B1) in blood serum. TGF-B1, in a dose-dependent manner, is believed to inhibit epithelial proliferation.[12,13] In serum, the concentration of TGF-B1 has been found to be five times that of tears. A 20% solution keeps TGF-B1 levels in check (albeit at the expense of other key constituents, like epidermal growth factor). A controlled study comparing the safety and efficacy of 20% vs. 50% serum is certainly needed.

In order to obtain a 20% solution, 10cc of saline is removed from a 50cc bag; then, 10cc of 100% serum is added and mixed with the remaining 40cc of saline. So, a single blood draw produces 100cc of 20% ASEDs. This quantity of mixed autologous serum can yield 50 sterile 3ml dropper bottles, each containing 2ml of ASEDs. Given that 1ml equals about 20 drops, each bottle yields approximately 40 eye drops.

Relative Risks and Complications

The complication rate from ASEDs is relatively small.[14] In studies involving 255 patients, the following complications were reported:

- Peripheral corneal infiltrate and ulcer (n=1)
- Eyelid eczema (n=2)
- Microbial keratitis in patients with an epi-defect (n=3)
- Increased discomfort or epitheliopathy (n=5)

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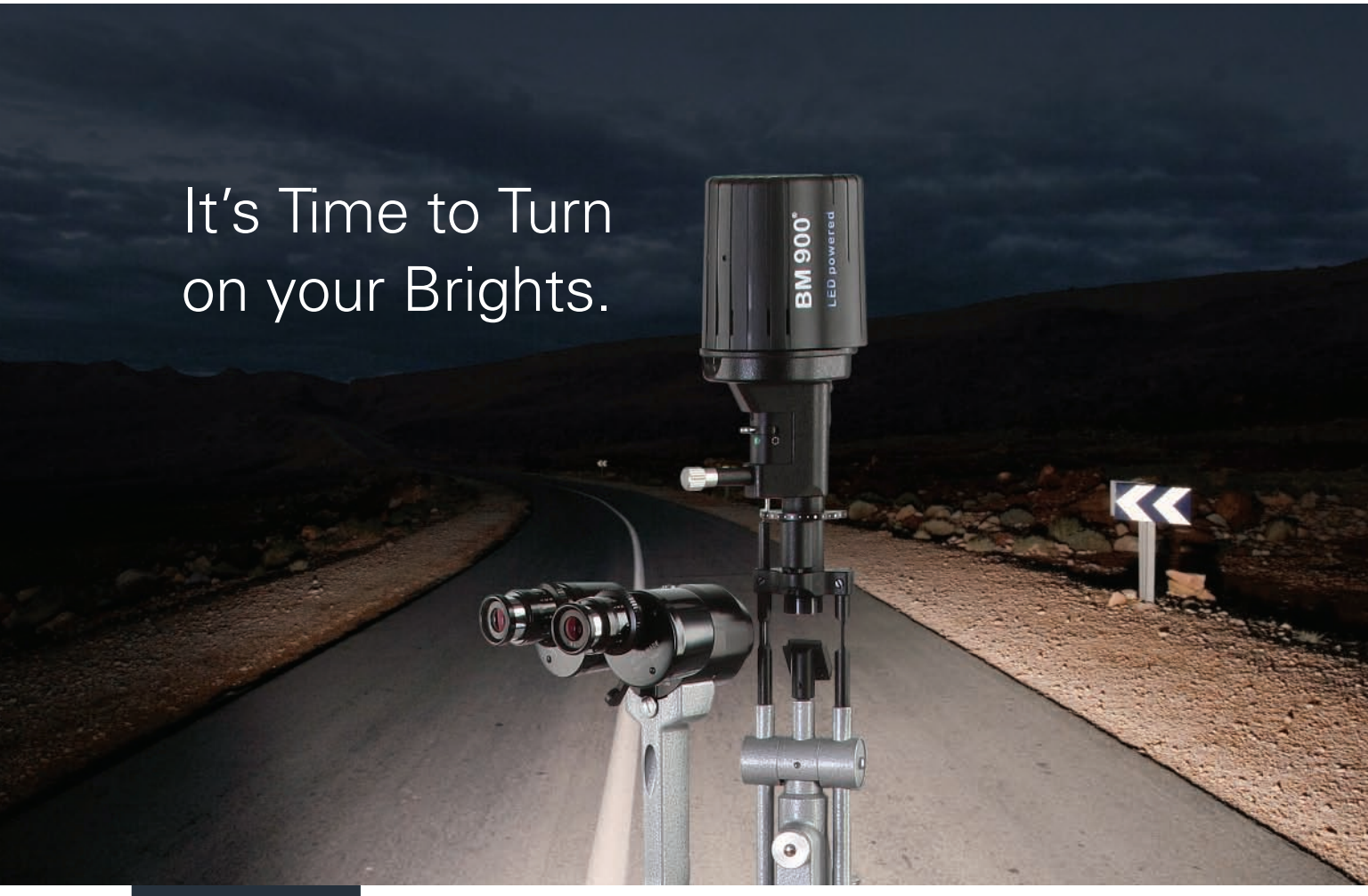

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The collected blood is set aside to clot for two hours at room temperature. Then the blood is centrifuged at 5,600 rpm for 10 minutes.

The serum is filtered through a 25mm polyethersulfone disc filter before mixing with saline. Filtration is performed to remove fibrin strands, which are believed to lessen the effect of ASEDs. Each 8.5cc tube of blood yields approximately 4cc of serum (24cc total).

• Temporary bacterial conjunctivitis (n=5)

• Scleral vasculitis and melting in RA patients

• Immune complex deposition with 100% serum

Bear in mind that some of these complications may have been due to the underlying disease state (i.e., uncontrolled rheumatoid arthritis) rather than a direct side effect of ASEDs.

Because ASEDs are preservative free and innately non-allergenic, there is minimal concern about toxicity from frequent dosing with the 20% formulation. However, hourly dosing of 100% serum has demonstrated immune complex deposition, so careful monitoring is still warranted with this formulation.[15]

When stored and used properly, the risk of serum contamination and denaturing are low. In one study of the sterility of non-preserved 20% ASEDs stored in a refrigerator, investigators found that no contamination occurred in their samples as far as three months out.[16] The epitheliotrophic components in serum were also shown to remain stable for at least one month in a refrigerator and for three months in a freezer.[17]

Of course, with frequent dosing comes increased handling and greater variability in patient compliance regarding use and re-refrigeration. Because the risk of contamination and serum denaturing increases with lapses in refrigeration or extended single-bottle use, patients and/or caregivers must be re-educated at each visit on the importance of protocol adherence. For instance, two cases of microbial keratitis were reported when bottles of ASEDs were used for a week at a time.[18] In one controlled, hospital-based study for the treatment of epithelial defects, contamination of preservative-free ASEDs did not occur until day four.[19]

In our practice, we dispense the serum tears in 3ml bottles and encourage a dosing regimen of every two hours while awake. This ensures that each vial will be empty within 24 to 48 hours of being refrigerated, which should prevent contamination.

While it is possible to formulate ASEDs with a preservative, preservative-free ASEDs are recommended because preservatives can negate the positive effects of the serum.[20] This recommendation comes from a study that involved culturing the first and last drop of ASEDs used by 14 patients from day four to day 14. In testing a total of 134 samples, only one grew a significant ocular pathogen (*S. aureus*). None of the bottles grew fungi after 24 hours of use.

Direct and Indirect Costs

In our practice, the cost for the blood draw and a three-month supply of ASEDs is $300. All patients are required to sign an Advanced Beneficiary Notice, or ABN, explaining the associated out-of-pocket expense for the drops, which are not covered by medical insurance. Assuming that the patient continues with therapy, the

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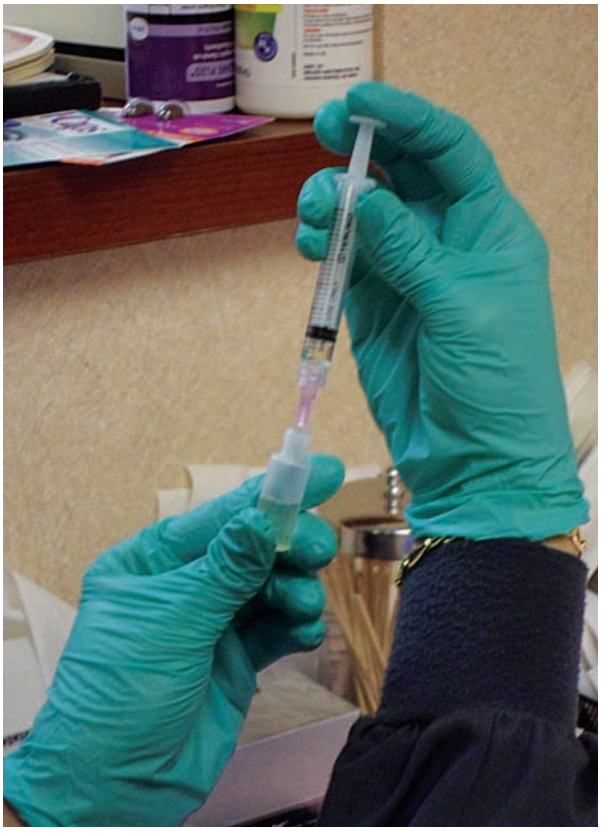
In order to obtain a 20% solution, 10cc of saline is removed from a 50cc bag; then, 10cc of 100% serum is added and mixed with the remaining 40cc of saline. So, a single blood draw produces 100cc of 20% ASEDs. Note the slight yellowish color to the 20% serum mixture. A quantity of 100cc of mixed autologous serum can yield of 50 dropper bottles, each containing 2ml of ASEDs.



Two milliliters of 20% autologous serum is delivered into a sterile 3ml bottle.

average annual direct cost approximates $1,200 dollars. Examination and follow-up visits are billed through insurance as usual.

While the direct cost of ASEDs may be a barrier for some patients, it is important to educate them on the cumulative indirect cost savings. As with the patient described above, many of our other patients have been able to reduce or eliminate more than one of their OTC or prescription eye drops while using ASEDs.

Given that 1ml equals about 20 drops, each bottle yields approximately 40 eye drops.

Patients with Sjögren's syndrome, such as our patient described in this article, often have ocular symptoms that are recalcitrant to conventional dry eye therapies. Even in the most controlled environments, dry eye symptoms can become severe enough to adversely affect a patient's quality of life.[21] Although autologous serum is not conventional therapy, it can certainly be effective therapy for these patients.

Our patient, for instance, has had no adverse effects from the serum drops and has maintained good vision and comfort for more than a year of treatment. He is happy that our practice took the time to research the science behind the serum, and he continually reminds us of how much more comfortable his eyes have become since starting ASEDs.

When conventional therapy isn't working for your severe dry eye patients, consider giving ASEDs a try. ■

Dr. Mangan is Center Director at the Eye Center of Richmond, a multispecialty comanagement practice in Indiana and Ohio. He is chair of the refractive surgery and clinical research committees for the Eye Center of Richmond and is an adjunct clinical professor at the Indiana University School

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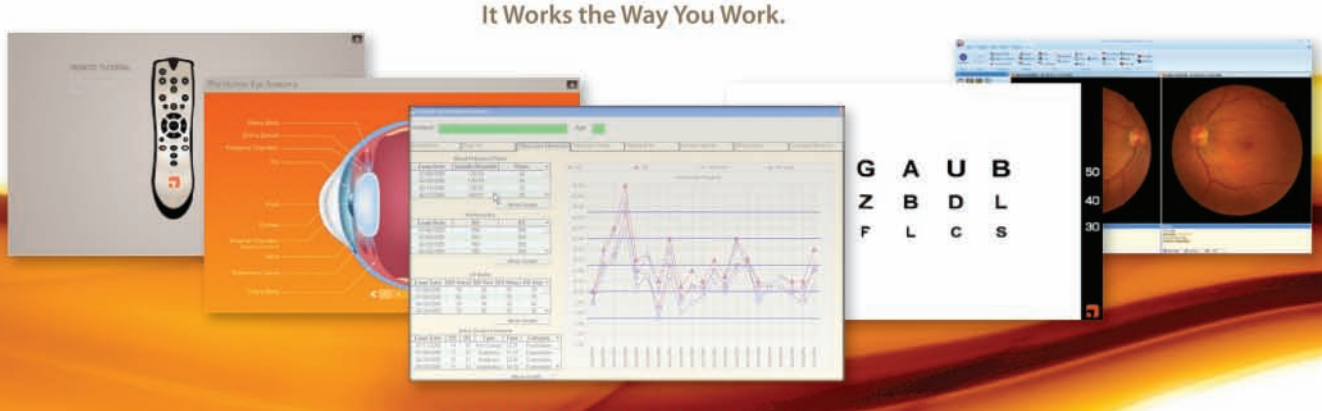

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of Optometry. Ms. Lehman is a certified ophthalmic assistant and team leader at Eye Center of Richmond, as well as a certified phlebotomist.

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INDICATIONS AND USAGE

LASTACAFT® is an H_1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

MECHANISM OF ACTION

Alcaftadine is an H_1 histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation have also been demonstrated.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Patients should be advised not to wear a contact lens if their eye is red.

LASTACAFT® should not be used to treat contact lens-related irritation.

Remove contact lenses prior to instillation of **LASTACAFT®**. The preservative in **LASTACAFT®**, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of **LASTACAFT®**.

LASTACAFT® is for topical ophthalmic use only.

ADVERSE REACTIONS

The most frequent ocular adverse reactions, occurring in < 4% of **LASTACAFT®** treated eyes, were eye irritation, burning and/or stinging upon instillation, eye redness, and eye pruritus.

The most frequent non-ocular adverse reactions, occurring in < 3% of subjects with **LASTACAFT®** treated eyes, were nasopharyngitis, headache, and influenza. Some of these events were similar to the underlying disease being studied.

Please see adjacent page for the Brief Summary of the full Prescribing Information.

1. LASTACAFT® Prescribing Information. **2.** Torkildsen G, Shedden A. The safety and efficacy of alcaftadine 0.25% ophthalmic solution for the prevention of itching associated with allergic conjunctivitis. *Curr Med Res Opin.* 2011;27(3):623-631. **3.** Data on file, Allergan, Inc., 2005; Clinical Study Report 05-003-11. **4.** Data on file, Allergan, Inc., 2005; Clinical Study Report 05-003-13. **5.** MediMedia Formulary Compass, November 2011.

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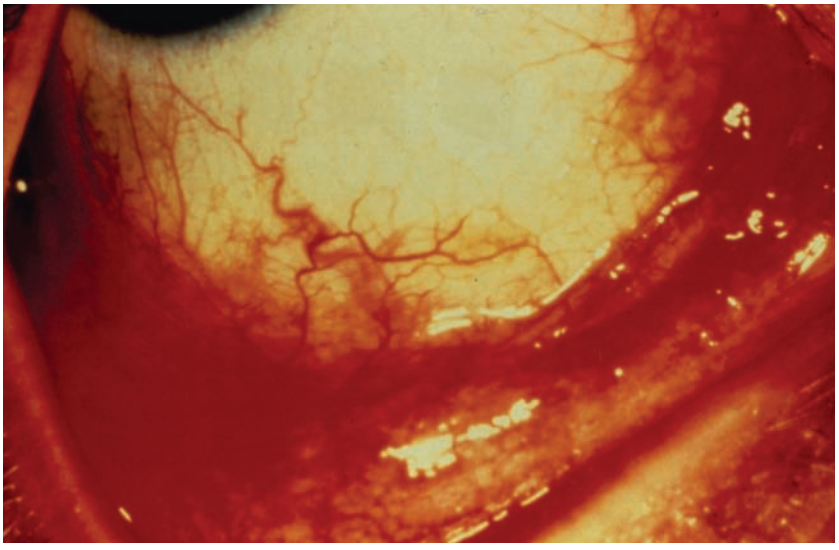
Spring Into Action this Allergy Season

With seasonal allergies expected to start earlier this year, it's never too soon to make sure you're up to date with the latest treatment options. **By Paul J. Gomes, M.S.**

As the final remnants of winter thaw and the new season takes hold, we anticipate the growth and renewal that comes with this time of year. Spring brings a slow but steady increase in outdoor activity, and the inevitable arrival of the first blooms of flowers and trees—followed quickly by the first sneezes and eye rubs of yet another allergy season.

Seasonal and perennial allergies are a significant global health issue affecting approximately 15% of the world's population; these percentages are even higher in the industrialized countries of Western Europe, Eastern Asia, Australia and North America.[1] In the United States, seasonal and perennial allergies affect 20% of the population, and 70% to 80% of these patients report that their allergies include ocular symptoms.[1,2] While not life threatening, the symptoms of ocular allergy can have a significant impact on quality of life for those who experience them.



Patients with chronic allergic conjunctivitis may experience itching, redness and burning of the eyes as well as excessive tearing.

Ocular allergy, or allergic conjunctivitis (AC), is typically cited as one of the most frequent reasons patients seek medical treatment for seasonal allergies.[2,3] Recent estimates put the annual economic impact of seasonal allergies in the United States at $7 billion, including almost $1 billion in work absenteeism.[2]

While there have been improvements in therapy over the past two decades, there has also been an increase in prevalence of the disease.[2,3] In addition, most

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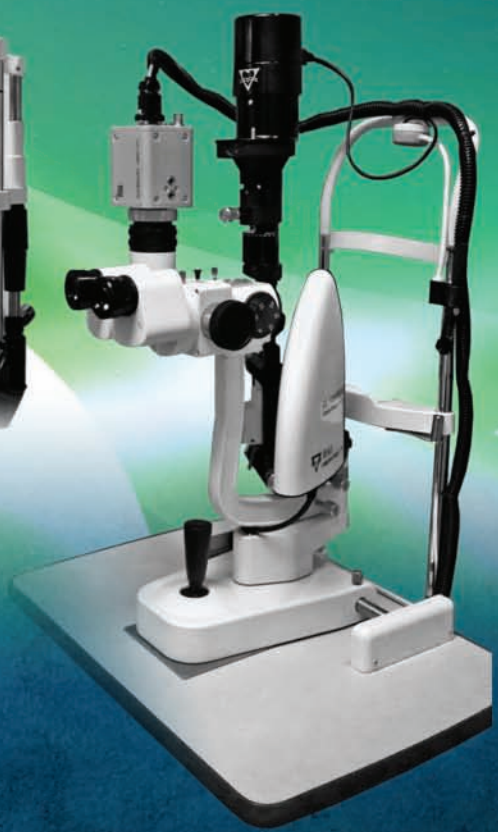

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of the drugs currently available to treat AC target ocular itching, leaving other signs and symptoms, such as ocular redness and chronic inflammation, untreated or under-treated.

As we prepare for this coming season, let's take a look at the current treatments for ocular allergies, review the therapeutic developments in years past and describe areas where future efforts could have the most impact.

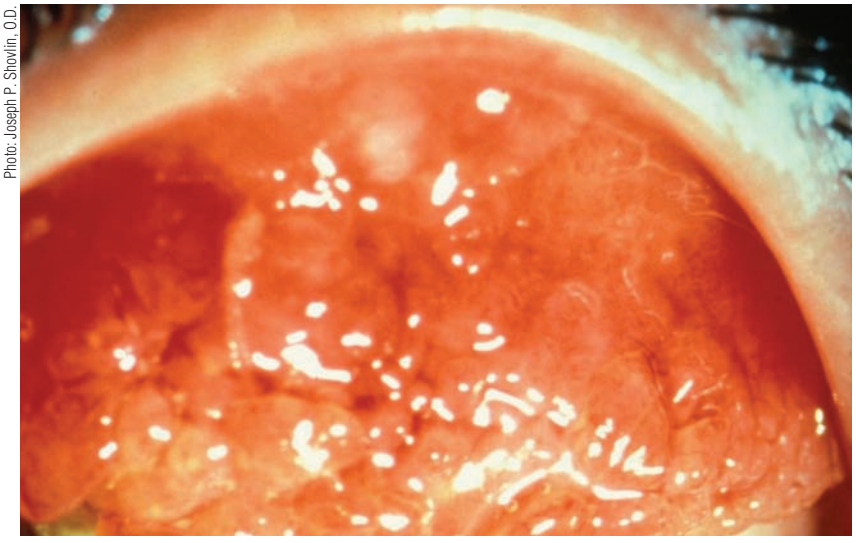

Photo: Joseph P. Shovlin, O.D.

The patient shown has severe vernal conjunctivitis, with a marked papillary response.

Changes in Treatment

Specific pharmacological treatments for ocular allergy were nonexistent prior to the early 1970s; typically, patients were instructed to use cold compresses and to avoid the offending allergen.[4,6] The first topical agents developed to treat AC were adrenergic agonists (such as naphazoline)—these drugs were effective at reducing hyperemia but did little to treat ocular itching.[9]

A second group of drugs, the mast cell stabilizers, first became available for topical ophthalmic use in the 1980s.[10,11] While these drugs showed efficacy in reducing ocular itch, they were relatively short-acting, and were also limited by the nature of their mechanism of action; because they are preventive treatments, they must be taken before the allergen is present to be effective.[12]

As we discuss below, patients typically used anti-allergics as needed, regardless of label (or practitioner) instructions and so, for the mast cell stabilizers, the arrival of symptoms is too late for drug treatment.

The first topical H1-antihistamines for ocular use (pheniramine and antazoline) came to market in 1990.[13,14] These were relatively short-acting medications, but were marketed as topical combinations of antihistamines and adrenergic agonists, creating a formulation that could treat both ocular itch and ocular redness. Some of these formulations are still available today as non-prescription topicals, but they have been replaced in recent years by superior, single-agent antihistamines.

In the last two decades, a number of second-generation H1-antihistamines have been developed to improve upon earlier drugs in terms of duration of action, safety profile and comfort. Important drugs in this group include levocabastine hydrochloride and emedastine difumarate, both of which were available as single-agent topicals.[15-17] While still requiring multiple daily dosing, both of these agents are highly effective in reducing ocular itch.

A progression of antihistamines followed, including azelastine hydrochloride, bepotastine besilate, ketotifen fumarate and olopa-

Causes and Conditions

Like other allergies, AC is caused by a type-1 (IgE-dependent) hypersensitivity reaction.[2] Exposure to allergens triggers mast cell release of inflammatory mediators, including histamine, that induce symptoms such as ocular itching and hyperemia.[4,5] Additional symptoms include swelling of the surrounding eyelids, chemosis and tearing.[4-6] Conjunctival swab cultures provide an unequivocal differential diagnosis of an infectious vs. allergic etiology, but the key feature that distinguishes AC from other forms of conjunctivitis is itching.

More severe, chronic forms of ocular allergy include rare conditions such as atopic keratoconjunctivitis (AKC), vernal keratoconjunctivitis (VKC) and giant papillary conjunctivitis (GPC).[6-8] Both AKC and VKC are allergic conditions in which the inflammatory response has been exacerbated to the point of significant conjunctival erythema and significant risk of corneal ulceration. In contrast, GPC is a condition specifically associated with contact lens use, and is due to a response to allergens deposited in the contact. All three of these conditions tend to be chronic, and are typically treated with a combination of antihistamines, mast cell stabilizers and topical steroids.

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AZOPT® Suspension, an adjunctive partner to a PGA that has IOP-lowering efficacy all day and all night[4]

INDICATIONS AND USAGE
AZOPT® Brinzolamide Ophthalmic Suspension 1% is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

DOSAGE AND ADMINISTRATION
- Instill one drop in the affected eye(s) three times daily
- If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten (10) minutes apart

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
- Hypersensitivity to any component of this product

WARNINGS AND PRECAUTIONS
- Sulfonamide hypersensitivity reactions
- Corneal edema may occur in patients with low endothelial cell counts

ADVERSE REACTIONS
Most common adverse reactions are blurred vision and bitter, sour or unusual taste.

Before prescribing AZOPT® Suspension, please read full prescribing information on adjacent page.

References:
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BRIEF SUMMARY OF PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AZOPT® (brinzolamide ophthalmic suspension) 1% is a carbonic anhydrase inhibitor indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

2 DOSAGE AND ADMINISTRATION

The recommended dose is one drop of AZOPT® (brinzolamide ophthalmic suspension) 1% in the affected eye(s) three times daily. If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten (10) minutes apart.

3 DOSAGE FORMS AND STRENGTHS

Solution containing 10 mg/mL brinzolamide.

4 CONTRAINDICATIONS

AZOPT® (brinzolamide ophthalmic suspension) 1% is contraindicated in patients who are hypersensitive to any component of this product.

5 WARNINGS AND PRECAUTIONS

5.1 Sulfonamide Hypersensitivity Reactions

AZOPT® (brinzolamide ophthalmic suspension) 1% is a sulfonamide and although administered topically it is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of AZOPT® (brinzolamide ophthalmic suspension) 1%. Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration.
If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

5.2 Corneal Endothelium

Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing AZOPT® (brinzolamide ophthalmic suspension) 1% to this group of patients.

5.3 Severe Renal Impairment

AZOPT® (brinzolamide ophthalmic suspension) 1% has not been studied in patients with severe renal impairment (CrCl < 30 mL/min). Because AZOPT® (brinzolamide ophthalmic suspension) 1% and its metabolite are excreted predominantly by the kidney, AZOPT® (brinzolamide ophthalmic suspension) 1% is not recommended in such patients.

5.4 Acute Angle-Closure Glaucoma

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. AZOPT® (brinzolamide ophthalmic suspension) 1% has not been studied in patients with acute angle-closure glaucoma.

5.5 Contact Lens Wear

The preservative in AZOPT® (brinzolamide ophthalmic suspension) 1%, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of AZOPT® (brinzolamide ophthalmic suspension) 1%, but may be reinserted 15 minutes after instillation.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

In clinical studies of AZOPT® (brinzolamide ophthalmic suspension) 1%, the most frequently reported adverse events reported in 5-10% of patients were blurred vision and bitter, sour or unusual taste. Adverse events occurring in 1-5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus and rhinitis.

The following adverse reactions were reported at an incidence below 1%: allergic reactions, alopecia, chest pain, conjunctivitis, diarrhea, diplopia, dizziness, dry mouth, dyspnea, dyspepsia, eye fatigue, hypertonia, keratoconjunctivitis, keratopathy, kidney pain, lid margin crusting or sticky sensation, nausea, pharyngitis, tearing and urticaria.

7 DRUG INTERACTIONS

7.1 Oral Carbonic Anhydrase Inhibitors

There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and AZOPT® (brinzolamide ophthalmic suspension) 1%. The concomitant administration of AZOPT® (brinzolamide ophthalmic suspension) 1% and oral carbonic anhydrase inhibitors is not recommended.

7.2 High-Dose Salicylate Therapy

Carbonic anhydrase inhibitors may produce acid-base and electrolyte alterations. These alterations were not reported in the clinical trials with brinzolamide. However, in patients treated with oral carbonic anhydrase inhibitors, rare instances of acid-base alterations have occurred with high-dose salicylate therapy. Therefore, the potential for such drug interactions should be considered in patients receiving AZOPT® (brinzolamide ophthalmic suspension) 1%.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Developmental toxicity studies with brinzolamide in rabbits at oral doses of 1, 3, and 6 mg/kg/day (20, 62, and 125 times the recommended human ophthalmic dose) produced maternal toxicity at 6 mg/kg/day and a significant increase in the number of fetal variations, such as accessory skull bones, which was only slightly higher than the historic value at 1 and 6 mg/kg. In rats, statistically decreased body weights of fetuses from dams receiving oral doses of 18 mg/kg/day (375 times the recommended human ophthalmic dose) during gestation were proportional to the reduced maternal weight gain, with no statistically significant effects on organ or tissue development. Increases in unossified sternebrae, reduced ossification of the skull, and unossified hyoid that occurred at 6 and 18 mg/kg were not statistically significant. No treatment-related malformations were seen. Following oral administration of ^{14}C-brinzolamide to pregnant rats, radioactivity was found to cross the placenta and was present in the fetal tissues and blood.

There are no adequate and well-controlled studies in pregnant women. AZOPT® (brinzolamide ophthalmic suspension) 1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

In a study of brinzolamide in lactating rats, decreases in body weight gain in offspring at an oral dose of 15 mg/kg/day (312 times the recommended human ophthalmic dose) were seen during lactation. No other effects were observed. However, following oral administration of ^{14}C-brinzolamide to lactating rats, radioactivity was found in milk at concentrations below those in the blood and plasma.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from AZOPT® (brinzolamide ophthalmic suspension) 1%, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

A three-month controlled clinical study was conducted in which AZOPT® (brinzolamide ophthalmic suspension) 1% was dosed only twice a day in pediatric patients 4 weeks to 5 years of age. Patients were not required to discontinue their IOP-lowering medication(s) until initiation of monotherapy with AZOPT®. IOP-lowering efficacy was not demonstrated in this study in which the mean decrease in elevated IOP was between 0 and 2 mmHg. Five out of
32 patients demonstrated an increase in corneal diameter of one millimeter.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

10 OVERDOSAGE

Although no human data are available, electrolyte imbalance, development of an acidotic state, and possible nervous system effects may occur following oral administration of an overdose. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity data on brinzolamide are not available. The following tests for mutagenic potential were negative: (1) *in vivo* mouse micronucleus assay; (2) *in vivo* sister chromatid exchange assay; and (3) Ames *E. coli* test. The *in vitro* mouse lymphoma forward mutation assay was negative in the absence of activation, but positive in the presence of microsomal activation. In reproduction studies of brinzolamide in rats, there were no adverse effects on the fertility or reproductive capacity of males or females at doses up to 18 mg/kg/day (375 times the recommended human ophthalmic dose).

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tadine hydrochloride.[18-21] Each of these compounds is classified as a "dual-action" antihistamine because they exhibit both H1 receptor antagonism and mast cell stabilization effects.[12]

In addition to this dual-action effect (or perhaps because of it), these newer drugs all have a longer duration of action than either levocabastine or emedastine. They are indicated for twice-daily dosing to relieve itching due to AC.

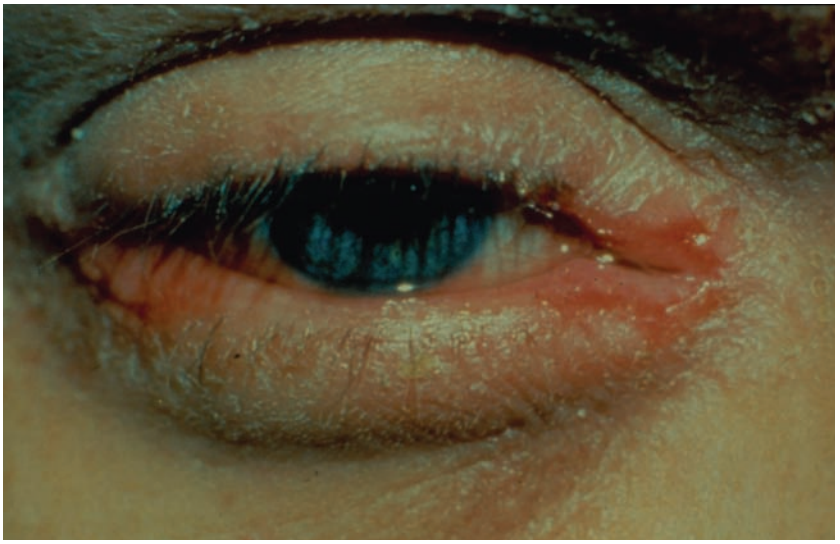
Most recently, two agents have been approved for once-daily dosing—a higher concentration formula (0.2%) of olopatadine hydrochloride, (Pataday, Alcon), and the newest ocular antihistamine, alcaftadine (Lastacaft, Allergan).[22,23]

A noteworthy aspect of histamine antagonists is that, unlike the pure mast cell stabilizers, these drugs are effective whenever the patients experience allergic symptoms. This was a significant step forward, and many would say it changed the landscape of ocular allergy therapy. In addition, the high efficacy of these drugs meant that most patients moved from an everyday, "prevention-based" dosing to a more "as-needed" use.

Ironically, it's possible that antihistamine/mast cell stabilizers could be more effective if used prophylactically; evidence suggests that prevention of acute allergic responses may be one way to minimize the growing trend toward chronic allergies.[24] Daily use of topical antihistamine/mast cell stabilizers during allergy season would be likely to have such an effect.

Treating Poor Responders

Despite this continued improvement in AC therapy, many patients with ocular allergies (some estimates put the number at 30% in the U.S.) show poor response to most currently available therapies.[1] These poor responders to antihistamine therapy appear to fall into two groups: chronic allergics and seasonal allergics.



With atopic keratoconjunctivitis, the lower eyelid is typically affected more than the upper lid and the conjunctiva lining the eyelids is usually red and swollen.

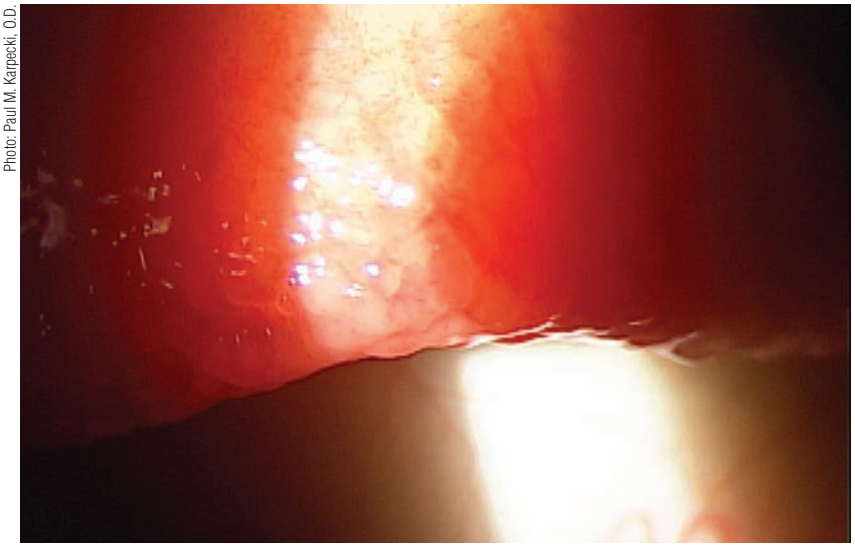
The first group consists of those with the combination of seasonal and perennial allergies; for these patients, it is always allergy season. The second group includes patients with robust responses to seasonal allergens, so that on days with particularly high pollen levels they present an allergic response that simply overwhelms the ability of any topical antihistamine to suppress.

In the last two decades, a number of second-generation H1-antihistamines have been developed to improve upon earlier drugs in terms of duration of action, safety profile and comfort.

Both types involve conjunctival recruitment of immune cells in addition to mast cells, and so the goal of any new therapy is to "calm" the conjunctiva, allow the recruited cells time to dissipate and also reduce the inflammatory features of the chronic, late phase response. These patients can be considered chronic ocular allergy sufferers, and they are symptomatically similar to those with more severe allergic conditions such as AKC.

Chronic allergy differs from the more acute forms in that it is primarily mediated by cellular factors, and is dependent upon the activity of immune cells such as basophils and eosinophils that have infiltrated the conjunctiva over the course of prolonged allergen exposure.[24] The increased prevalence of chronic atopic diseases such as AC in recent years, especially in more industrialized countries, is thought to be a result of increased

Photo: Paul M. Karpecki, O.D.



Patients with asthma, hay fever or animal allergies may be at greater risk for GPC; its etiology may be immunological, where contact lens deposits act as allergens.

exposure to allergy-exacerbating agents, such as air pollutants and volatile chemicals.

Evidence suggests that these chemicals can prime the immune response to perennial allergens, such as dust mites and molds.[25] As the prevalence of these chronic poor responders increases, current and future anti-allergic drug development must identify therapies to address this unmet need.

Currently, the best available treatments for chronic ocular allergy sufferers are topical steroids, such as prednisolone acetate or loteprednol etabonate.[12] While effective, these drugs are typically used for brief periods (courses of one to two weeks) to minimize the risk of adverse ocular effects such as cataracts or increases in intraocular pressure.

Newer anti-inflammatory compounds are likely candidates for future studies of chronic AC. Beyond trials of compounds with theoretical or demonstrable anti-inflammatory effects, however, it is necessary to establish a clear strategy for identifying and developing the next class of ocular anti-allergics.

Looking Ahead

Researchers at Ora, Inc. have spent the past 30 years developing and refining methods to test new drugs and formulations for ocular allergy. In that time, our conjunctival allergen challenge (CAC) model has become an industry standard, and has been employed for studies used to gain FDA approval for all ocular anti-allergics currently marketed in the U.S.[26] Recently, Japan's Pharmaceuticals and Medical Devices Agency also adopted the CAC model for allergic drug development. This means that testing of new anti-allergics for both the American and Japanese markets can be conducted simultaneously, and should speed drug development.

The success of clinical models such as the CAC underscores the fundamental importance of study design in the drug development process. The research group at Ora, like others in the ocular therapeutics industry, is focused on how to accurately assess the efficacy of either new chemical entities or repurposed drugs as therapies for chronic ocular allergy. Key to these efforts is the ability to accurately identify the "non-responder" population from the greater population of allergics.

In addition, trials need to employ robust experimental standards that elicit the chronic allergic signs and symptoms, similar to the CAC model for acute allergy. Future therapies will likely employ drugs that interfere with cytokine signaling, or those that can disrupt the intracellular processes that mediate this chronic feedback loop.

Results of pre-clinical studies have focused on a number of factors that define the chronic allergic subject. Prolonged or high levels of allergen exposure lead to infiltration and accumulation of basophils, eosinophils and increased numbers of mast cells. These cells respond to continued presence of allergens by releasing a smorgasbord of cytokines, chemo-attractants, proteases and other signaling molecules. The net effect is continued recruitment of immune and inflammatory cells, breakdown of the ocular surface's extracellular matrix and destabilization of the protective, barrier function of the conjunctival and corneal epithelium.[24] ■

Mr. Gomes is vice president of Allergy at Ora, Inc. Ora has provided clinical research services for each product mentioned.

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17th Annual Comanagement Report

What is 'Integrated Eye Care?'

Comanagement with ophthalmologists is nothing new. But, how we approach and execute this process has changed dramatically in recent years.

By Derek N. Cunningham, O.D., and Walt Whitley, O.D., M.B.A.

Today, optometry is undergoing major changes due to increased patient demands for medical care and a host of cutting-edge advancements in eye care technology. In conjunction with these changes, more skilled professionals are now needed to address patient needs.[1]

With the advanced aging of our population and the increased need for medical eye care, various "integrated eye care" models have been developing all around the country. This article explains why and how integrated eye care has developed in the United States and what key benefits and limitations this practice model includes.

History of Integrated Eye Care

Optometry and ophthalmology have always had a working relationship—although, historically, this relationship operated at arm's distance. For years, O.D.s made referrals to ophthalmologists with some lingering uncertainty about if or when the patient would return.

Traditionally, optometrists have concentrated on vision care needs while ophthalmologists have been the sole providers of medical specialty eye care. But, during the last 30 years, there has been a significant change in the scope of optometric practice with the expansion into medical eye care as well as the development of multiple optometric subspecialties.

Advantages of Integrated Eye Care Delivery

- Utilizes the strengths of each practitioner.
- Improves efficiency in patient care.
- Establishes a natural checks-and-balances system.
- Provides a better understanding of patient needs.
- Matches the procedure to the patient.
- Enhances profitability.
- Increases surgical volume.

Currently, optometrists in all 50 states can prescribe topical ocular medications. Additionally, O.D.s in all but three states (Florida, Massachusetts and New York) can prescribe oral medications. And more recently, the optometry boards of West Virginia and Kentucky won legislative battles that expanded the current scope of practice. With these changes, the relationship between optometry and ophthalmology has evolved into the wider integrated eye care model that we commonly see today.

The Numbers

Before we can discuss the need for integrated eye care, we must discuss the current and future demographics of practicing optometrists and ophthalmologists. Each year, more than 1,200 O.D.s graduate from American optometry schools. There have been numerous debates on whether the increased number of graduates is justified and legitimately required, or if it will inevitably lead to an oversupply of practicing optometrists. In 2008, there were approximately 34,800 practicing optometrists with a projection of 43,200 by 2018—a growth rate of 24%.[2]

Looking at the other side, the number of U.S. ophthalmologists is expected to increase from 15,000 in 2008 to 15,101 by 2015. This change includes an estimated addition of 3,124 new ophthalmologists over the seven-year period and the

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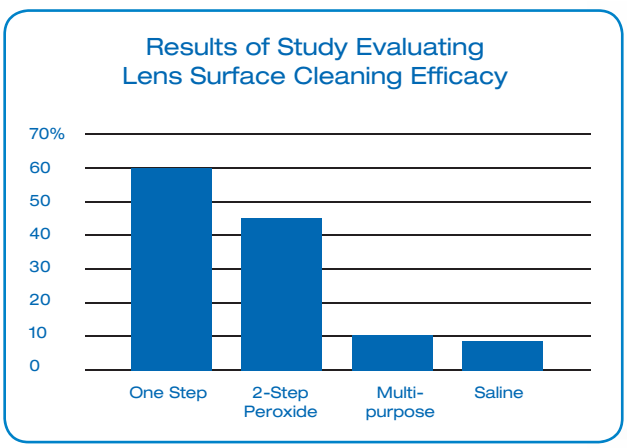

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*Independent research study performed at prestigious UK University. Data on file.

Common Issues Faced in the Integrated Eye Care System

- Need for constant, seamless communication.
- Patients sometimes do not understand the different role each practitioner plays.
- Inherent complexity of the O.D./M.D. relationship.
- Some laws affect the ability to provide patient care.

anticipated retirement of 3,023 ophthalmologists.[2]

From 2008 to 2015, the number of cataract/IOL surgical procedures alone will increase from an estimated 3,092,000 to approximately 3,851,000.[3] Additionally, patients requiring treatment for vitrectomies, refractive surgical procedures, glaucoma management, macular degeneration and vision-threatening diabetic retinopathy will also increase, justifying the need for the expanded role of optometrists to address the non-surgical aspects of these conditions.

Just looking at the numbers alone, now more than ever, the contributions of each profession will be needed to adequately care for our patients.

The Value of the O.D. in Comanagement

The importance of each primary care optometrist remaining involved throughout the referral process cannot be over-emphasized. Here's why:

- Optometrists have gained a level of trust and familiarity with their patients. No one has a better understanding of patients' visual needs, requirements and ocular/medical history. We help educate our patients about their conditions, the reason for the referral and the treatment options available. We communicate the knowledge of our patients' conditions as well as their preferences back to the surgeons. And, we plan on seeing these patients return to us.
- Continuous communication between the referring optometrist and ophthalmologist serves as a check-and-balance system for patient care, drug interactions and/or potential surgical complications.
- Optometrists serve as the care coordinator for patients with multiple disease states who see a variety of specialists. A similar example would be a primary care physician who coordinates care between a cardiologist, optometrist and neurologist.
- Optometrists serve as an additional resource for patients, should problems arise. Many times, it is much easier and more convenient to see us than to see a busy surgeon.

Integrated Eye Care Models

So, the question remains—what is integrated eye care? An integrated eye care practice can take many forms, and it is up to all care providers to determine which model best fits their patients and their practice needs. By our assessment, there are four basic integrated eye care models:

- **Optometrists in private practice who actively comanage patients.**
- **Optometrists who work directly with ophthalmologists in a referral center.**
- **Optometrists who partner/employ/lease space with ophthalmologists.**
- **Optometrists who practice in a vertically-integrated setting (O.D./M.D./optical).**

Private Practice Optometric Comanagement Model

The private practice optometric comanagement model is the most common form of integrated eye care. Optometric comanagement shares the responsibility of patient care through optometric referral networks and ophthalmologists. In this relationship, optometrists refer patients solely for secondary/tertiary care.

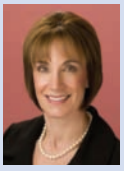
Depending on the practice type, location, insurance coverage and individual situation, optometrists have the opportunity to participate in both the perioperative and long-term care of patients.

For those practitioners who focus

Perspectives from an O.D. in Private Practice

- ***Sherri Becker, O.D.; Becker Eye Care, Hampton, Va.***

Integrated eye care delivery provides full service care to patients, including primary, secondary and tertiary. This can be accomplished either in one practice or in the model that I use—teaming with a referral center.



I have an excellent relationship with the ophthalmologist referral center. I perform primary and some secondary eye care, and the ophthalmologists provide secondary and tertiary eye care. Each M.D. has a specialty and is therefore an expert in their area. The advantage of this model is that patients are provided with all levels of eye care, which reduces the duplication of more general services. The end result is more efficient and cost-effective care for the patient.

However, one limitation of this model is that extreme consideration must be taken to ensure continuous and uninterrupted patient care. So clear, consistent communication between all comanaging clinicians is a must.

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References: 1. Based on a post-launch evaluation in which 88 eye care practitioners refit over 400 patients in AIR OPTIX® AQUA contact lenses. Alcon data on file, 2011. **2.** Nash W, Gabriel M, Mowrey-Mckee M. A comparison of various silicone hydrogel lenses; lipid and protein deposition as a result of daily wear. *Optom Vis Sci*. 2010;87:E-abstract 105110. **3.** Compared to HEMA contact lenses; based on the ratio of lens oxygen transmissibilities; Alcon data on file, 2010. **4.** Dumbleton K, Richter D, Woods C, et al. Compliance with contact lens replacement in Canada and the United States. *Optom Vis Sci*. 2010;87(2):131-139. **5.** Compared to 2-week replacement lenses; based on self-reported lens replacement time and third-party industry pricing information; Alcon data on file, 2012.

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specifically on refractive and vision needs, referrals are made to address only medical eye conditions, such as glaucoma and retinal disease. The referring optometrist will see their patients for future primary eye care needs. In cases where patients may need additional testing or imaging, a referral center can be used as an extension of the optometrist's practice to have necessary tests performed without seeing a specialist. Patients benefit from the comanagement model because their optometrist always remains the quarterback of their care.

Referral Center Comanagement Model

Optometrists in a referral center facilitate the care and communication between the private practice O.D. and the ophthalmic surgeon. In addition to clinical care, many optometrists serve administrative

Perspectives from O.D.s in a Referral Center

• Paul Ajamian, O.D.; Center Director of Omni Eye Services, Atlanta

Integrated eye care is a group of doctors with different specialties who work together for the common good. Within our model, the relationships that we have with ophthalmology are, for the most part, very good. But, as in any relationship, it is easier to work with some people more than others, which can be both an asset and a challenge.

The advantage of our referral facility is the constant communication between our practice and our referring O.D.s. Being a teaching facility, we work closely with fourth-year student externs and residents. This environment helps them understand the working relationships we have with ophthalmology.

One of the limitations of our model is that we cannot (and will not) see patients without a referral from an O.D. While many practices make money from dispensaries and direct referrals, we do not. Unfortunately, our loyalty to the model doesn't really mean as much as it should to O.D.s these days.

For instance, some O.D.s refer to M.D. practices that have large optical dispensaries or that market directly to the public. By doing so, they are sending patients (and potential revenue) to their competition, which doesn't make sense and doesn't help promote the private optometric practice.

• Tracy Swartz, O.D., M.S.; Center Director of Vision America, Huntsville, Ala.

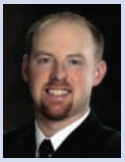
I believe that the integrated eye care concept is exemplified as: primary care delivered by an optometrist; surgery performed by ophthalmologists; and communication facilitated by both parties. Both functional and medical needs are met efficiently using support staff, and the referral center is viewed as an extension of the optometric practice.

The advantage of our model is the full scope of practice that is enjoyed by both optometry and ophthalmology, which is encouraged by consistent continuing education and case consultation. Optometrists who take ownership of the medical practice model fully support it, and the surgeons do well within their area of specialty without the hassle of primary care.

The limitation of our model is that the optometric advisory board is not directly associated with the center or the M.D.s; yet, the board is permitted a level of authority regarding center operations. That authority includes the ability to govern the direction of the practice as well the capacity to terminate M.D.s and O.D.s. Additionally, working with surgeons can be trying at times, because individual personalities vary. Most interestingly, many of our M.D.s have met resistance from their peers for supporting optometry.

• Chris Freeman, O.D.; Clinical Director at TLC Laser Eye Centers, Oklahoma City

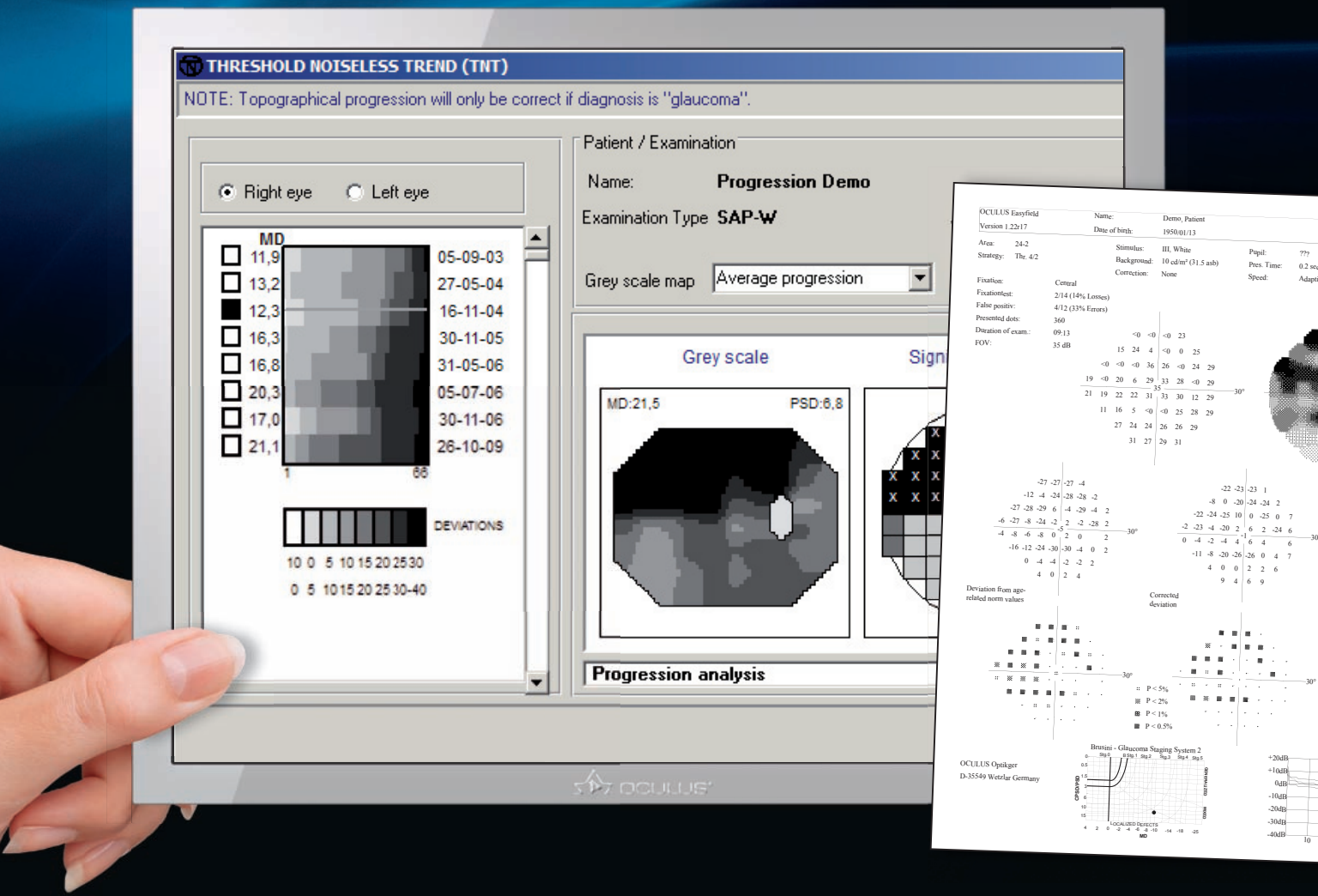
I define integrated eye care as optometry and ophthalmology working together to provide convenient, competent patient care in both surgical and medical comanagement. Each profession has its strengths and limitations when it comes to a patient-first philosophy, where the care provided by one side can nicely complement that of the other. This relationship is very similar to how an internist may work with a cardiologist or endocrinologist.



The main advantage of integrated eye care is working off of one another's strengths to accentuate the positives in overall patient care. Many patients have seen their primary eye care providers for several years, and are most comfortable continuing to see them for future routine care. Our comanagement model fosters this continuity of care. For surgeons who like to do surgery and non-surgeons who like to do eye exams, this setup works well.

Another advantage is pre-screening by the referring doctor for refractive surgical procedures. Patients can be screened for keratoconus or ocular surface disease, be treated accordingly, and referred for surgical care if appropriate. Such early detection and counseling can make for a more streamlined patient experience and better results.

The biggest limitation for our model is patient logistics. For some patients—depending on where they live—it would be easier to perform all their surgical testing at the same time as the preoperative exam with their referring eye doctor. Another limitation is communication. With more people involved in the process and with busy doctor schedules, there may be occasional communication breakdowns, which can result in some redundant counseling or testing.



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Perspectives from O.D.s who Partner with or Employ M.D.s.

• Greg Moore, O.D.; Clinical Director of West Virginia Laser Eye Center, Charleston, W.Va.

In my mind, integration is not as much "between me and my surgeons," as it is "between the surgeons and the referring O.D.s." The total integration of care throughout a community puts patients in the hands of the provider who is best suited to care for them.

Clinical eye care is the domain of the optometrist, and the operating room is the domain of the surgeon. Reducing the surgeon's chair time increases his or her time in the operating room. And, in this capacity, patients are given the best available care in both the clinic and the operating room setting.

One prerequisite of integrated care is that there must be mutual respect and genuine appreciation for the other parties involved. Patients can detect if the relationships between clinicians are uneasy or unprofessional.

The advantage of our practice model is that our surgeons can perform a high number of procedures on patients who are first evaluated by the O.D. Consequently, we are able to increase the productivity of our surgical center, which helps to improve postoperative outcomes and overall patient satisfaction.

• Jill Autry O.D., R.Ph.; Partner, Eye Centers of Texas, Houston

Integrated eye care utilizies the training and capabilities of all types of eye care professionals—from ophthalmologists and optometrists to ophthalmic assistants and technicians—in a combined, collaborative approach. Because we don't provide primary care, refractions or contact lenses, it is the O.D.'s responsibility to triage patients, perform pre- and postoperative care, and provide follow-up care for optometrist-referred patients. Each O.D. partner also has various office responsibilities as well as optometric comanagement duties.

One advantage of this model is that our O.D.s act as liaisons between the community O.D.s and the surgeons in our practice. This allows our optometrists to practice completely on the medical side of eye care as well as provide a safe haven for the local optometrists.

The main drawback for our referral center model is the lack of long-term patients. Most of our patients are taken care of and returned to their referring physician without the development of longer, personal relationships.

roles and support optometric referral networks. The only care that is provided by optometrists in a referral center is purely medical in nature, including pre- and postoperative treatment (cataract, refractive, etc.). Perioperative optometrists serve as a valuable resource for answering questions about surgical requirements, complications and postoperative management, as well as addressing patient concerns from the referring doctors.

Referral centers provide minimal to no long-term eye care, and patients are always sent back to the referring O.D. as soon as it is safe to do so. Additionally, there is no conflict of interest regarding refractive care, so patients must return to their referring optometrists for any optical needs.

Partnered/Employee Comanagement Model

Another aspect of integrated eye care occurs when optometrists either hire surgeons to work within their practice or lease office space to ophthalmologists. This arrangement most often occurs in rural or small-town settings where there is an undersupply available surgeons—although this doesn't have to be the case. Optometrists maintain their own practice and utilize surgeons on a weekly, biweekly or monthly basis to provide additional care. This way, patients do not need to be referred elsewhere or drive several hours to receive care.

Vertically-Integrated Comanagement Model

Within a vertically-integrated practice, O.D.s address all aspects of primary eye care, prescribe glasses and contact lenses, and treat a variety of disease states as their comfort and licensure allows. If a condition falls outside of the scope of optometric practice, patients are referred to an ophthalmologist who can concentrate on advanced disease management and surgery.

In this modality, each party complements the other, which improves overall efficiency while keeping the patients in the same practice. Ancillary staff members contributing to this model include certified ophthalmic technicians and opticians.

The result of a vertically-integrated practice is efficient treatment and surgical stabilization of patients. When a patient sees the surgeon for a preoperative exam, there are no delays or surprises. This process facilitates a regimented and reliable preoperative exam process and streamlines scheduling for the patient and the surgeon. Additionally, the surgeon's clinic time is minimized, allowing more operating time to be scheduled.

Although there is no singular definition of what constitutes integrated eye care, we definitely have noticed improved relationships between optometry and ophthalmology. Ultimately, this has resulted in better care for our patients.

Perspectives from an O.D. in a Vertically-Integrated Practice

• Scott Hauswirth, O.D.; Minnesota Eye Consultants, Minneapolis

To me, integrated eye care means having a center where both optometry and ophthalmology work side-by-side in a collegial fashion to solve the problems presented to us by our patients. Our practice has multiple M.D.s, and our relationships with them are very good. There is mutual respect and exchange of ideas on how to best care for patients.

The advantage of our model is the efficiency of care. Patients have easy access to optometrists as the front line of eye care, and we can refer to the ophthalmologists for surgical needs. This keeps our surgeons doing more surgery, and our O.D.s are empowered to provide clinical care at a very high level. Our model also provides access to developing technologies and fosters new and innovative treatment options that are not always initiated or implemented by the ophthalmology side.

I think the only limitation of our model comes from those individuals who do not understand what can be accomplished by working together. In a mutually supportive environment, everyone succeeds—our patients, our doctors and staff, our practice and our professions as a whole.

With the additional emphasis in ocular disease treatment and management in optometric education, O.D.s are adequately prepared to diagnose and treat the majority of conditions that we see in our clinics.

When conditions fall outside of the scope of practice or the comfort level of our peers, we have working relationships with our colleagues in ophthalmology to help address these concerns. With optometry being a clinically based practice, and ophthalmology being heavily surgical in nature, we are seeing the two professions utilize each other's strengths—even under the same roof. Unquestionably, the most successful integrated practices will follow the theory of "let clinicians be clinicians, and let surgeons be surgeons." ■

Dr. Cunningham is the director of research and optometry at Dell Laser Consultants, in Austin, Texas. Dr. Whitley is the director of optometric services at Virginia Eye Consultants, in Norfolk, Va.

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17th Annual Comanagement Report

Steep Competition: LRIs vs. Toric IOLs

Limbal relaxing incisions have been the go-to treatment for astigmatism after surgery. But, will the more reliable toric IOLs take the place of LRIs? By Aaron Bronner, O.D.

Astigmatism has been the bane of refractive eye care for years. Change to a person's myopic glasses prescription typically generates little to no concern; but if you rotate the axis of astigmatism by a few degrees, many patients report dramatic effects on their spatial perception. Spherical contact lenses are tolerant of rotation and decentration, but a toric contact lens that rotates just 10 degrees after a blink is a common source of patient frustration.

Astigmatic laser refractive surgery has become accessible only years after myopic treatments had been around. With current cataract surgery, postoperative astigmatism has become a cringe-worthy event. In the era of small-incision cataract surgery—where good uncorrected acuities are not only routine, but expected by patients—residual refractive error is considered (by patients, at least) a negative outcome.

Unfortunately, postoperative astigmatism isn't an unusual event. In one very large study of a cataract population, corneal astigmatism between 0.75D and 1.50D was present in more than 40% of patients, with higher levels in nearly 20%.[1] Historically, this figure has dovetailed poorly with our ability to treat astigmatism. Intraocular lens technology has been primarily spherical in its refractive properties, and until recently correction of corneal astigmatism has been an afterthought based on wound positioning and corneal incisional surgery. As technology has increased, however, so too has our ability to treat astigmatism.

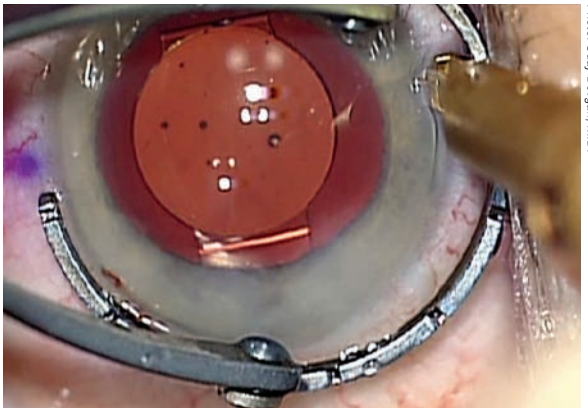

Photo: Uday Devgan, M.D.

A limbal relaxing incision is commonly combined with a toric IOL when the need for astigmatism correction exceeds the toricity of currently available IOLs.

So, in this age of baby boomers with both cataracts and astigmatism, what are their options—and what does the science say about them?

Limbal Relaxing Incisions

For years, our go-to option for expected post-cataract surgery astigmatism has been the limbal relaxing incision, or LRI.

LRIs are based on the same principle as all-incisional refractive surgery; that is, a partial-thickness cornea incision leads to flattening of the cornea—a premise that dates back to Dr. Herman Snellen in the mid-1800s.[2] Technically, LRI is a tissue addition procedure (like other incisional refractive surgeries); as the gaped wound heals, it fills with scar tissue and results in a flattening of that meridian. The surgeon makes an arcuate or tangential partial thickness incision just onto the clear cornea. The incision is along the steep axis of astigmatism, with its depth and length determined by

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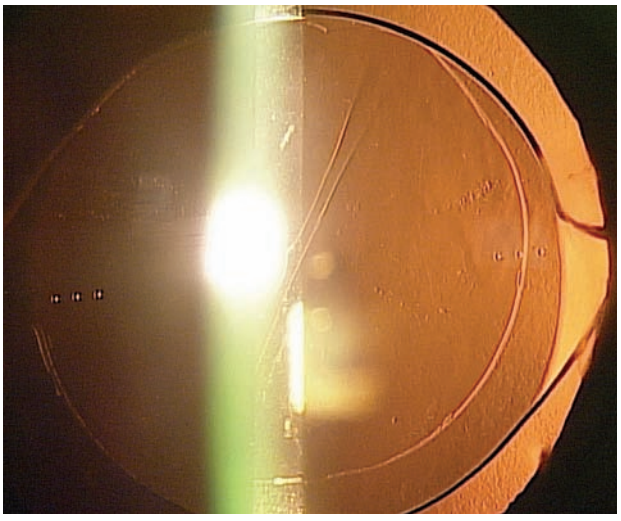
the amount of astigmatism to be treated; a longer (up to 90 degrees) and deeper cut leads to greater dioptric flattening.

Photo: Walter Whitley, O.D.



Newer-generation toric IOLs are designed for better stability and less rotation than previous toric implants. They're also coming out in greater ranges of astigmatic correction.

By comparison, in astigmatic keratotomy (an older procedure), the incisions were placed within the central corneal zone, which led to greater refractive impact per incision size, but also greater refractive instability.

The reason for an LRI performed during a cataract operation is to correct any astigmatism that exists at the corneal plane, as IOLs have traditionally utilized spherical or aspheric optics. The procedure can be done along with the cataract while on the operating room table, and it offers a low risk, cost-effective means of minimizing expected postoperative astigmatism.

The strengths of LRI are its simplicity and ease of use: It's a comparatively non-invasive procedure that can safely correct corneal astigmatism, and the flexibility of incision placement allows the correction of some amount of irregular astigmatism as well. For example, we recently had a 41-year-old male in our clinic for a LASIK evaluation. He saw 20/30 O.U. uncorrected, and his only refractive error was 1.50D of simple astigmatism. Instead of LASIK, we suggested a less expensive, less invasive LRI first. The patient agreed and the surgery soon took place. At his one-month follow-up, the patient was 20/15 and thrilled to have saved some of the cost of surgery. In short, LRI does maintain its place in clinical and surgical practice.

More commonly, we combine an LRI with a toric IOL for an astigmatism correction that exceeds the toricity of currently available IOLs (a magnitude that seems to be ever expanding).

The weakness of LRI is the procedure's unpredictable nature. Despite well-known nomograms for incisional depth and length for refractive effect, it is not a 100% accurate or consistent response. LRI is described quite succinctly as "more art than science," says Robert Osher, M.D., medical director at Cincinnati Eye Institute.[3]

Unfortunately, it's not rare to have minimal impact on refractive cylinder with LRI, despite following the nomograms. In one study of LRI paired with cataract surgery in 55 eyes, the mean preoperative corneal astigmatism was 1.90D, which was reduced to 1.00D by six months post-op.[4]

A study of the effects of LRI for mixed corneal astigmatism showed a similar result with roughly 3.30D of preoperative cylinder, which was reduced to 1.60D postoperatively.[5] This lack of predictability and accuracy has created the niche for a more consistent means of correcting astigmatism, particularly in conjunction with cataract surgery.

This is where toric IOLs are gaining ground.

Toric IOLs

In theory, an implanted toric lens that has good capsular support should be stable within the eye and provide correction of astigmatism. Optically, the magnitude of this correction will be about 70% the toricity of the lens. Said differently, an IOL with 3.00D of toricity will correct about 2.00D of corneal astigmatism.

One retrospective study compared the theoretical benefit of a toric IOL vs. a spherical IOL and LRI.[6] Of the patients who received the toric IOL, mean uncorrected visual acuity averaged 20/30, while those who received the mixed procedure achieved 20/40 vision on average. As many as 70% of toric IOL patients saw 20/30 or better, compared to 51% of those receiving LRIs.

However, one of the drawbacks of the toric lens used in this study, STAAR Toric IOL (STAAR Surgical), was rotational instability.[6] About 18% of patients showed rotation between 20 to 40 degrees, and 7% had greater than 40 degrees of rotation. All IOLs were able to be repositioned, but the result was illustrative of the problems that occurred with older-generation toric IOLs.

While older toric lenses were

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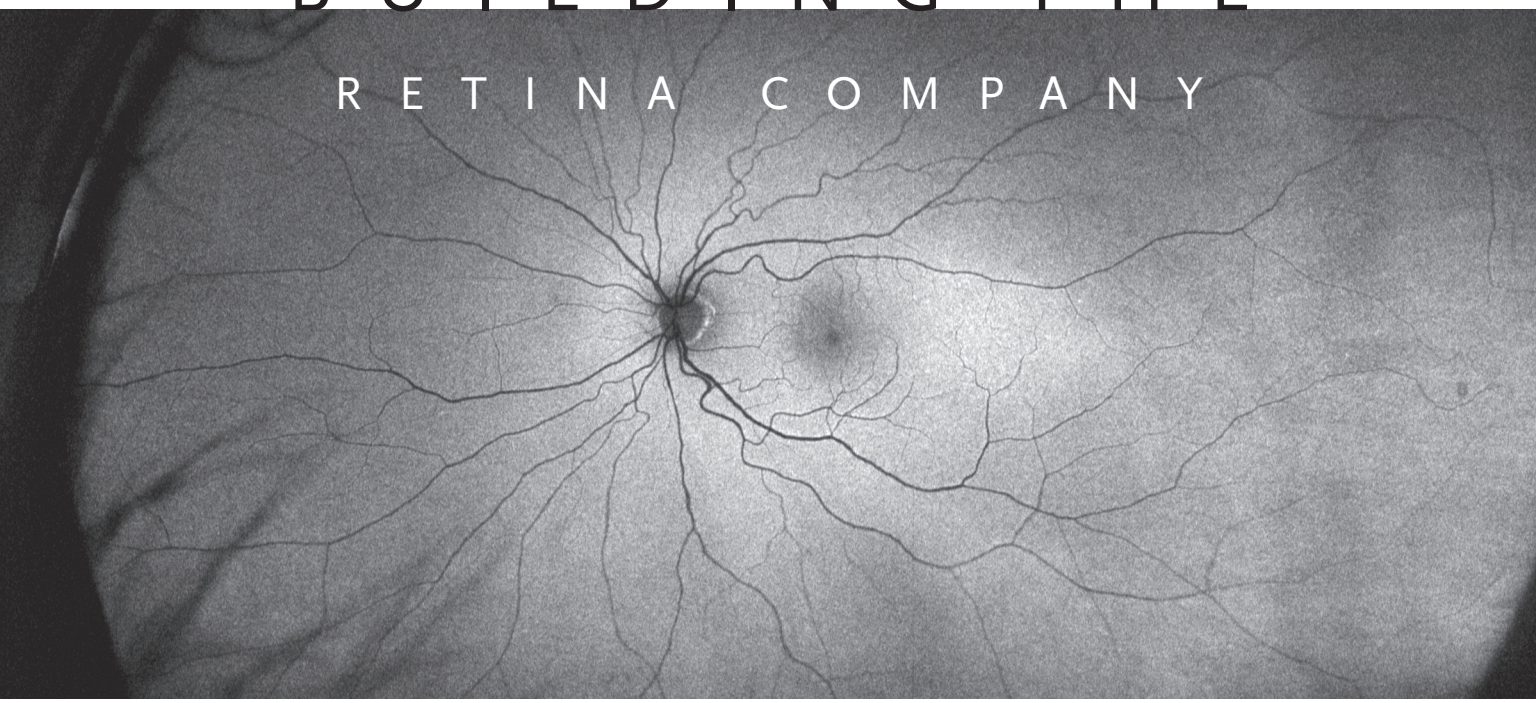

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LRI Revisited: LenSx and LRI

The LenSx (LenSx Lasers, distributed by Alcon) is a device that has been making waves in cataract surgery centers during the last year or so. While it's often marketed as "laser cataract surgery," this is an oversimplification of both the device and the surgeon's role in surgery.

The LenSx is a femtosecond laser instrument that, rather than replacing the surgeon, assists with some key features of surgery, including creation of clear corneal incisions, creation of the capsulorhexis, and lens fragmentation. Stabilization of the globe, completion of phacoemulsification, removal of the lens particles, and IOL implantation are still in the hands of the surgeon.

One of the interesting features of the LenSx—in relation to corneal astigmatism and cataract surgery—is its ability to use the laser to also create LRI incisions. The laser uses a novel nomogram to determine incision magnitude.

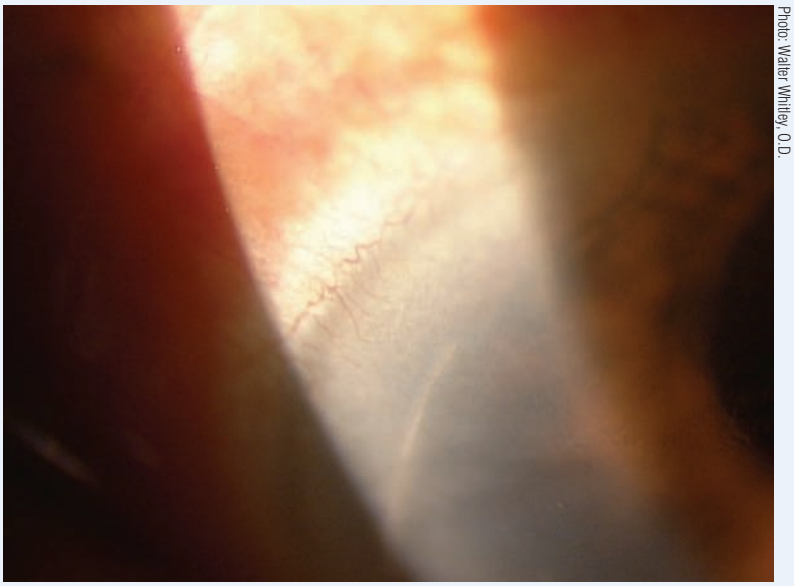

Photo: Walter Whitley, O.D.

A limbal relaxing incision created by femtosecond laser.

"The first thing that struck me about the LRIs generated with LenSx is how clean the incisions look," says David Coulson, O.D., of Barnet Dulaney Perkins Eye Centers, in Arizona, whose practice utilizes the LenSx. "Secondly, the incisions are a little more central, coming a couple millimeters in from the limbus. This makes them a bit like a hybrid LRI/astigmatic keratotomy."

Time will tell if laser-generated LRIs are more stable or predictable than the bladed variety. But, according to Dr. Coulson, results so far have been encouraging. "It does seem like the predictability of the incision and level of control with it has enhanced outcomes," he says.

Still, Dr. Coulson points out that this technology is supplemental for postoperative astigmatism and doesn't replace toric lenses. "We use the technology to treat lower levels of corneal astigmatism. When the toricity gets to 1.25D [and above], we still recommend the toric IOL options."

an improvement over LRIs, they also unfortunately suffered from issues of stability and predictability—the premise upon which they were based.[6,7]

This rotational instability is significant because toric lenses lose 3.3% of their astigmatic correction for each degree of misorientation. At 30 degrees net misrotation, there is no net astigmatic correction. At 30 degrees off axis, the lens actually creates refractive astigmatism.

The newer generation AcrySof IQ Toric IOL (Alcon Surgical) was designed to minimize these shortcomings. The lens shares a similar design with the AcrySof Single-Piece IOL, a lens that was designed with stability-enhancing features such as more stable haptics and a bioadhesive polymer base. While such features may sound like creative marketing, these modifications actually seem to work. For example, Ed Holland, M.D., of the Cincinnati Eye Institute and one of the world's foremost anterior segment specialists, conducted a study to assess stability and visual outcomes with this IOL.[7] The study results showed good stability with minimal rotation (a mean of 3.8 degrees).

Of the 256 implants in this study, only three rotated by more than 15 degrees over the year of follow-up. Two-thirds (65%) of the patients who received the toric IOL had uncorrected acuity of 20/25 or better, compared to 29% of the controls who received the AcrySof spherical lens.[8]

Another study on bilateral AcrySof Toric implants showed axis alignment within five degrees in 91% of patients and within 10 degrees in 99% of patients.[9] This equated to good visual outcomes for patients—uncorrected acuities of 20/40 or better in 99% of patients, and 20/20 or better in 60%.

Also, it's helpful to have implants that come in a range of corrections. There are seven different AcrySof Toric lens options correcting corneal cylinder from 1.00D through more than 4.00D.

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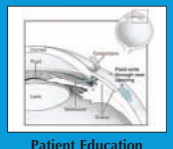
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options available, "I prefer the toric IOL options to LRI. I've found their predictability to be superior to that of LRIs," says Douglas Devries, O.D., co-owner of Eye Care Associates of Nevada, a large surgery practice. "That's not to say I never recommend LRIs. Sensitive patients with less than 0.75D of cylinder—those who fall below the scope of the toric IOL—are fine candidates."

Dr. Devries also considers LRI for astigmats with cylinder beyond the scope of correction with the lens. "In these cases, we'll use a combined toric IOL/LRI procedure," he says.

Toric IOL or LRI: What Do Surgeons Prefer?

When faced with a patient with astigmatism, 57% of surgeons say they prefer to use toric IOLs, according to a survey in *Review of Ophthalmology*. Thirty-one percent like limbal relaxing incisions, 7% place their entry incision on-axis, and 5% use a post-op refractive procedure to handle the astigmatism.

Comanagement Care

From a referring optometrist's standpoint, there is very little additional data that needs to be gathered at the preoperative exam to utilize the toric lens. In order to determine if astigmatism will be present after surgery, manual or topographic keratometries could be performed; however, this will be repeated at the surgery center.

Discuss toric IOLs with all patients who have refractive astigmatism. In most cases, this is a fair indication if there will be residual cylinder after surgery. If a referring optometrist doesn't bring up the different IOL options with their patient prior to cataract surgery, the O.D. is essentially relinquishing any advisory role in the process to the surgeon.

This discussion doesn't need to be exhaustive—it's sufficient to simply make the patient aware of the lens options available and offer any professional preference you have.

Postoperative follow-up for toric lenses is only slightly more technical than with standard IOLs or LRIs. In addition to the normal postoperative exam, toric lenses require evaluation of lens orientation under dilation. If the lens is rotated significantly (such that the patient appreciates the difference), a surgical repositioning is in order.

Early rotation (rotation that occurs in the first postoperative month) is much more common than late rotation.[6-8] This often coincides with typical postoperative follow-up because most three- or four-week follow-ups involve dilation and allow assessment of lens position.

Misorientation of the lens by any degree that contributes to patient dissatisfaction or recalcitrant refractive astigmatism should be referred back into the surgery center for repositioning.

Repositioning of the lens is an effective means of treating the problem—but the timing of it is important.[6] "Referring O.D.s need to know the intended axis of rotation and evaluate it closely," Dr. Devries says. "It's very important to understand that the critical time for repositioning of these lenses is within the first month. Repositioning [during this period] is more effective and leads to greater stability in the long run."

There is a definite evolution going on within our cataract patient base. The baby boomer population views cataract surgery not only as a means to see better with correction, but also as a refractive procedure in itself. To meet this demand, reliable IOL technology has been developed to aid in the neutralization of postoperative astigmatism. With no additional drawbacks outside of occasional rotation issues and cost passed onto the patient, toric IOLs are also very safe devices to use.

In summary, "One of the keys to postoperative success—and we hear this all the time with multifocal IOLs—is managing and meeting patient expectations. With astigmatic corrections, it's no different," Dr. Devries says. "The toric lenses give the patient a better chance of achieving the outcome I discussed with them. This makes me look good and it makes for a happy patient." ■

Dr. Bronner is in practice at Hollingshead Eye Center, a secondary care center in Boise, Idaho. He has no financial interest in any of the products or companies mentioned.

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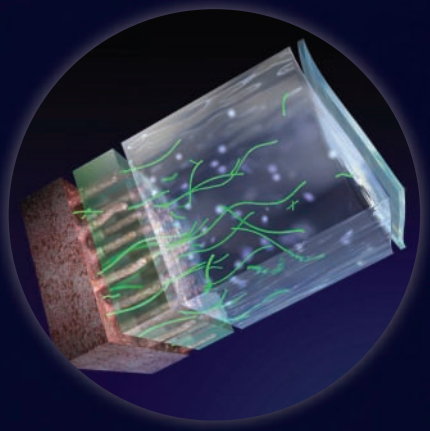
DRY EYE IS A DISEASE WHICH MAY PROGRESS AND IMPACT PATIENTS' LIVES

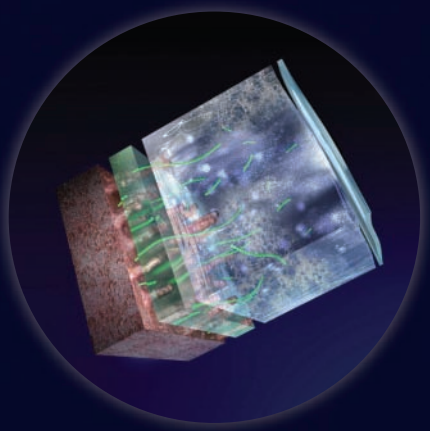
Dry Eye is a multifactorial disease that may result in discomfort, visual disturbance, and tear film changes. Inflammation, hormonal imbalance, age, and environmental triggers all play a role.[1,2] These factors set in motion a self-perpetuating series of events that affect the ocular surface, lacrimal glands, meibomian glands, and the neural network.[1,3-5] This changes tear quantity and quality, which can damage the corneal epithelium, the tissue protected by the tear film, resulting in:[5]

- **Increasing symptoms** As the disease alters the tear film and the ocular surface, patients can experience grittiness, foreign body sensation, burning, and itching.[1,6]
- **Increasing visual alterations** Small changes—such as reduced viscosity or thickness—may significantly impact vision quality, primarily contrast sensitivity.[1,7,8] These changes to the tear film and corneal irregularity may be responsible for blurred and fluctuating vision.[1]
- **Impact on daily activities** These visual alterations and symptoms can significantly increase difficulty with work, night driving, computer use, reading, and contact lens wear.[2,6] Working on a computer can become challenging as the eyes constantly strain to correct tear film changes.[6,7] Driving at night can become difficult due to fluctuating vision, reduced contrast sensitivity, and increased glare.[8]



THE HEALTHY TEAR FILM

Composed of mucin, aqueous, and lipid components, the healthy tear film is important to the eye's normal functioning. It optimizes visual refraction, protects the ocular surface, and facilitates tear spreading.[1]



THE DRY EYE TEAR FILM

The effects of Dry Eye on the tear film can result in symptoms, ocular surface damage, and visual disturbances, potentially impacting a range of daily activities.[1,2,6]

INITIATE THE DRY EYE DISCUSSION WITH YOUR NEXT PATIENT

Many patients may not mention their symptoms to an eye care professional because they are unaware they may be consequences of Dry Eye disease. Visit **FocusOnDryEye.com** to access important resources.

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ALLERGAN

An Overview of Visual Hallucinations

Patients who experience hallucinations secondary to a host of underlying conditions often will look to you for guidance, reassurance and treatment. **By Michael N. Block, O.D.**

Although healthy individuals may experience hallucinations, these visual phenomena are often associated with a variety of disease processes. Some patients who seek care for visual hallucinations first approach an internist or neurologist. However, a significant number of patients present to an optometrist when associated symptoms include headache, reduced visual acuity and restricted fields.

Bilateral vision loss predisposes some patients to intermittent visual hallucinations. The source of decreased vision may lie anywhere in the visual pathway, but macular degeneration is most often implicated. These frequently begin as simple visual hallucinations, and then progress to more complex ones. Patients usually recognize them as being distinct from reality and, after the initial few occurrences, consider the images to be both pleasant and non-threatening. This phenomenon likely is underreported because many patients fear that the hallucinations herald the onset of dementia.

Eighteenth-century Swiss scientist turned philosopher Charles Bonnet first documented visual hallucinations and impaired vision in the context of uncompromised cognition—thus, the constellation of associated symptoms later became known as Charles Bonnet Syndrome (CBS).[1]

Here, we'll discuss the occurrence of hallucinations in healthy patients as well as in those with a host of underlying conditions, such as stroke, migraine and Parkinson's disease. Additionally, we'll examine the particulars of CBS, including its pathogenesis, risk factors and management strategies.

Hallucinations

Perception is the awareness that results from the brain's processing and synthesis of data that is

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Goal Statement: This article examines the occurrence of hallucinations in healthy patients as well as in those with a host of underlying conditions, such as stroke, migraine and Parkinson's disease. Additionally, we'll examine the particulars of Charles Bonnet Syndrome, including its pathogenesis, risk factors and management strategies.
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garnered by our sensory organs. Imagery, unlike perception, occurs in the absence of adequate sensory input and lacks a sense of reality. Hallucinations differ from both perception and imagery because there are no sensory inputs that correspond to cortically generated visual experiences. Despite this, the images seem compellingly real. Although hallucinations stem from a variety of conditions, the actual visual symptoms are often quite similar, leading some researchers to suggest the existence of just a few common mechanisms that produce these phantom images.[1,2]

Visual hallucinations may be characterized as either simple or complex, depending upon their content. Simple (elementary) hallucinations include spots of light, lines and patterns, and are associated with the striate cortex. On the other hand, complex hallucinations yield vivid, formed, well-organized images, and are linked to the visual association areas. More specifically, complex hallucinations may feature images of people, faces, birds, animals or scenery. Additionally, miniature images (lilliputian) are often reported, and may be either dynamic or static.

No matter the form, when hallucinations occur in the visually impaired, the outstanding clarity of the phantom image sharply contrasts with the individual's habitually degraded vision.[1]

In one study of the cerebral cortex, the author discovered that electrical stimulation of the striate cortex (areas 17 and 18) caused simple visual hallucinations, including light flashes.[3] When the visual association cortex (area 19) was stimulated, the subject experienced complex visual hallucinations. The presence of hallucinations associated with area 19 in the context of calcarine cortical infarction supports the claim that hallucinations originate in the surviving visual association areas.[3]

Hallucinations in Healthy Patients

Complex visual hallucinations occur in 30% of individuals who have no predisposing physical or mental conditions. Such complex hallucinations are associated with varied states of drowsiness, and usually occur at the end of the day before the onset of sleep. They may persist for as little as two seconds to more than 15 minutes; the duration possibly is related to the degree and length of fatigue.[1]

Occasionally, hallucinations begin as simple before transitioning to complex. However, more often than not, hallucinations both begin and remain complex. Their content may range from terrifying to pleasant.

Hallucinations not only are related to periods of drowsiness prior to sleep in otherwise healthy patients, but also are found in—and epitomized by—narcolepsy. The hallmark of narcolepsy is excessive daytime sleep that is unrelated to the total sleep time of the prior evening. The episodes are uncontrollable and often interfere with normal activities.

During sleep, brain activity is divided into two categories based on physiologic changes and the presence of dreaming: non-rapid eye movement (NREM) and rapid eye movement (REM). NREM is the first stage of sleep and has four subcategories that usually need to be completed before entering into REM. Normally, NREM begins with shallow sleep; then progresses to deep sleep; and eventually leads into a period of REM, which is when most dreaming occurs. This process repeats itself several times each night.

The initial REM phase occurs 90 minutes after the onset of sleep, and persists for approximately 10 minutes. Each successive period of REM lasts longer—the final phase persisting up to one hour.

Hallucinations occur during the first REM period. In normal individuals, the first REM phase takes place only following the deepest NREM sleep. Unlike a dream, where the individual often is a participant, the hallucinator generally is an observer. The term "hypnagogic hallucination" was first used in 1848 to describe this phenomenon.

It is postulated that hypnologic hallucinations are generated when REM sleep is entered prematurely and/or when there is still a high level of cognitive arousal. These hallucinations—found in both normals and narcoleptics—are referred to REM-related abnormalities.[1] It is interesting to note that as many as 50% of narcoleptics experience hypnagogic-type hallucinations when transitioning from being awake to falling asleep.[1]

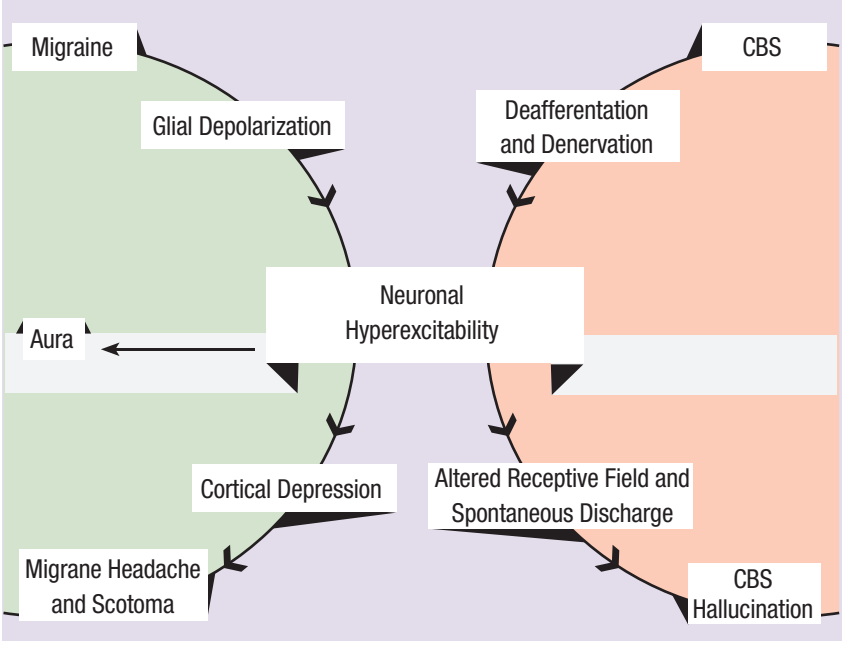
Posterior Cerebral Artery Infarction

The majority of cerebrovascular accidents (CVA) result secondary to embolic travel to the cerebral vasculature. This process causes an interruption in blood supply, which results in ischemia.

Hemorrhagic strokes are far less common, but may produce the same end result. Stroke patients with infarction of the middle cerebral artery often suffer from contralateral hemiparesis or weakness. Infrequently (10% of cases), infarction of this vessel will produce a contralateral hemianopsia.[4] The vast majority of CVA-related hamianopsias, however, are caused by infarctions of the posterior cerebral arteries.[4]

Complex visual hallucinations

The Evolution of Migraine Headache/Aura and CBS Hallucination



have been reported in 13% to 41% of patients who suffer hemianopsias secondary to occipital infarction.[5] Usually, the visual phenomena occur within the defective visual field. Hallucinations usually are transient, lasting days to weeks—although they may persist occasionally. Additionally, they are limited to the visual modality, except when areas other than the visual cortex are involved. Most often, there is a time delay from the ischemic event to the onset of hallucinations that may last up to several weeks.

Radiological studies have demonstrated that lesions associated with hemianopsias and visual hallucinations are significantly smaller than the more severe lesions that cause only hemianopsias without hallucinations.[5]

Apparently, a small portion of surviving cortex is necessary for the generation of hemianopic visual hallucinations. Larger lesions that extend anteriorly and destroy the visual association areas never are associated with hallucinations.[5]

Brainstem Lesions

Peduncular hallucinosis, first documented in 1922, results from vascular lesions to the rostral brainstem that affect the thalamus.[2] They resemble the aforementioned vivid hypnagogic hallucinations that occur in normal patients.

Phenomena duration varies from minutes to hours, occasionally lasting all day. There is a time delay of several days prior to the onset of these phantom images. Although the hallucinations usually subside after a few weeks, they may persist for years.[2] Typically, episodes occur toward the evening, but are unrelated to levels of drowsiness. Interestingly, no part of the visual pathway—beginning at the retina and terminating at the visual cortex—is directly involved.[2]

Epilepsy

Complex visual hallucinations occurring in epilepsy patients bear little resemblance to hypnagogic and peduncular hallucinations. These hallucinations are brief, fragmentary and occur in the context of seizures or their aftermath. Based on intracranial electroencephalogram, they originate from pathological irritation and excitation of the visual association cortex.[6]

Migraines

The prevalence of migraine headaches in the general population is 10%.[7] Approximately one third of migraines are preceded by simple visual hallucinations known as auras. Although there are many variations, the classic aura is the fortification spectra, which begins near fixation and features shimmering lights that are restricted to half of the visual field. They enlarge in an arc of zigzag-lines oriented at 60° and are further magnified as they move from fixation to the periphery.[7]

Immediately following this phase is the development of a scotoma or hemianopsia. According to a 2004 report from the International Headache Society, the aura of migraine slowly and gradually develops over a span of five minutes, and may persist up to 60 minutes.[8] This contrasts with the visual symptoms of occipital epilepsy, which are fragmentary and flickering.[7,8]

In addition to being associated with migraine and epilepsy, aura-like vision changes are found in some patients with occipital lesions. It is important to understand that this symptom overlap often poses a diagnostic challenge. Although these auras are infrequently associated with cortical lesions, the clinician still needs to differentiate the benign migrainous auras from those secondary to an intracranial pathology.[7]

A clinically important characteristic of the migraine aura is variability within the visual fields. The location often shifts laterally from

one hemifield to the next in different episodes. Approximately 86% to 100% of patients with cortical pathology have auras that are contralateral to the lesion.[7,9,10]

An aura that consistently recurs on the same side should alert the practitioner to a more insidious etiology and warrants imaging and referral. Similarly, any change in the appearance of a previously diagnosed migrainous aura or the emergence of a new aura also should be of concern. Several studies documented a significant increase (58% to 67%) in the frequency of visual auras among patients who were ultimately diagnosed with an intracranial pathology. Daily auras were reported in 32% of these patients.[7,9,10]

Migraine sufferers rarely see complex visual hallucinations. Such hallucinations are, however, frequently found in migraine coma (an entity associated with recovery from coma) and familial hemiplegic migraine. Further differentiating these hallucinations from migraine aura is the timing; unlike the aura of a conventional migraine headache, hallucinations caused by migraine coma and familial hemiplegic migraine occur at the end of the attack.

The electrophysiological correlate to the aura is a spreading wave of glial depolarization that is followed by reduction in cortical activity, which is known as cortical spreading depression (CSD). The rate of depolarization traversing the cortex directly corresponds to the rate of the scintillating scotoma's movement from the center to the periphery.[10]

Expanding upon this electrophysiological data, one study indicated that the initial migraine phase of aura is due to a chemically mediated state of neuronal hyperexcitability and spontaneous discharge associated with depolarization.[9] This is followed by CSD, which is responsible for the ensuing visual field defect and headache. The similarity of visual symptoms associated with cortical ischemia, intracranial lesions, epilepsy and migraines arises from the single common mechanism of CSD.[9]

Parkinson's Disease

Parkinson's disease is one of the most common neurological disorders associated with complex visual hallucinations. Between 8% and 40% of Parkinson's patients report these ophthalmic manifestations.[11,12] The hallucinations usually occur at the end of the day; are vivid and often associated with sleep disturbances; and may be similar to the peduncular hallucinations caused by brainstem lesions.[11,12]

Until recently, there was widespread acceptance that these hallucinations were due to adverse reactions to long-term use of Parkinson's medication levodopa. This theory was challenged by a prospective study in which the author concluded that underlying characteristics of Parkinson's—not the duration of medical treatment—were directly associated with hallucinations.[13] In fact, reduced visual acuity, depression, worsening of dementia and increased severity of Parkinson's disease were all more significant determinants of hallucinations than treatment duration.[1,13,14]

Schizophrenia

Hallucinations in schizophrenics usually are experienced in color and most often are multi-modal, consisting of visual and auditory components. They frequently accompany paranoia or other thought disorders. Unlike most of the hallucinations described above, these occur during the daytime and are associated with episodes of excess excitability.

Charles Bonnet Syndrome

Charles Bonnet documented hallucinations that were experienced by his 89-year-old grandfather, Charles Lullin. The images that Lullin described were varied and included people, animals, birds, scenery and carriages.

The onset of Lullin's spontaneously occurring images was linked to visual impairment that developed after bilateral cataract surgery. His cognition was intact, as was his ability to discern the hallucinations as unreal. This cognitive awareness has led some authors to characterize these visual phenomena as pseudo-hallucinations.[1] Interestingly, Bonnet—who was hearing impaired since childhood—suffered vision loss at age 34 and subsequently experienced visual hallucinations similar to those described by his grandfather.

Definitions

The defining characteristics of CBS have evolved since the condition was first described. In his essay, Bonnet indicated that advanced age, intact cognition, presence of eye disease and hallucinations with insight were all necessary components.[1]

In the 1930s, Georges de Morsier introduced the term CBS and used it to differentiate hallucinations that occurred with no cognitive deficits from those associated with cerebral degenerative disease.[1] Unlike Bonnet, de Morsier maintained that eye pathology was unrelated to the hallucinations and was not a prerequisite for the syndrome.

In 1950, Julian de Ajuriaguerra expanded the definition of CBS to include visual hallucinations in

the presence of eye disease. Building from this work, Klaus Podoll, M.D., established criteria to grade visual hallucinations seen by elderly patients who had normal cognition in the late 1980s. Interestingly, Podoll noted that visual acuity loss from eye disease was often—but not always—found.

Then, in 1989, Kenneth Gold, M.D., and associates took a different approach by defining CBS based on symptoms—not etiology. They suggested that CBS was a constellation of symptoms consisting of hallucinations that were exclusively visual, complex, formed and stereotyped with full or partial insight.[15]

Patterns

Complex visual hallucinations occur in 11% to 15% of patients who suffer severe bilateral vision loss. In CBS, simple visual hallucinations are documented more frequently than complex hallucinations, and affect up to 59% of patients.

One study indicated that the type of hallucination—whether simple or complex—was unrelated to the level of vision loss.[16] Furthermore, the extent of visual impairment was more predictive of CBS-related hallucinations than either the type or sub-type of underlying ophthalmic disease that caused the vision deficit.[16,17]

There is no definitive consensus regarding the condition's gender predilection; however, most studies suggest that women are more likely to be diagnosed with CBS than men.[1,16,18] And, although CBS has been reported in children who suffer sudden vision loss, the vast majority of CBS cases occur in the elderly—with an average age of onset ranging from 74 to 83 years. This age-related skew may be due to the increased prevalence of vision threatening eye disease in the geriatric population.[1,16,18]

Theory

Deafferentation is one of the current theories that explains the occurrence of complex visual hallucinations accompanied by severe bilateral vision loss.[1,19] It is associated with sensory deprivation and is based on the premise that a steady stream of high-quality input to the primary visual cortex is a prerequisite for proper, non-hallucinogenic, visual function.

The continual flow of non-degraded input to the striate cortex is crucial to suppressing the expression of random and memory-based images that are stored in the visual association areas. Retinal or other pathologies may interrupt this data stream, resulting in the reduced ability of the primary visual cortex to effectively censor or inhibit these images, which leads to their sudden intrusion into conscious perception. When this occurs, the images are then "released" and manifested as complex visual hallucinations.

The nervous system responds to denervation (loss of neuronal connections) and deafferentaion by biochemically inducing a state of neuronal excitability. This occurs in the visual, auditory, vestibular and motor systems.[20] It is thought that the cells in the visual association areas are, therefore, more likely to discharge spontaneously in this state of excitability due to the absence of quality afferent inflow.

One study evaluated the association of visual hallucinations and the activity of the occipital cortex using functional magnetic imaging (fMRI).[13] During the period when hallucinations were experienced, the authors documented reduced cortical response to visual stimulation. The occurrence of hallucinations underscored their assertion that these extraneous visual images arose from reduced sensory input and a resulting lack of visual association area inhibition.[13]

The CBS images are analogous to the auditory and musical hallucinations of the deaf, which are also attributed to sensory deprivation. Lack of quality input to the primary auditory areas reduces its inhibition of the auditory association areas. Likewise, the effect of degraded input on the primary visual cortex leads to a lack of censorship of extraneous images that originate in the visual association areas, which results in the expression of complex visual hallucinations.

Sensory deprivation can also cause tactile hallucinations that are similar to those experienced in "phantom limb syndrome," which is often seen in amputees (e.g., patients who have lost limbs frequently "feel" sensations or pain in the limbs that now do not exist). Similar to those affected by CBS, phantom limb patients are aware of the inauthenticity of these hallucinations, as well as display a latency period of weeks following the loss of sensory input before the tactile hallucinations begin.

In 1994, Peter V. Rabins, M.D., M.P.H., traced the similarities of hallucinations caused by either CBS or phantom limb syndrome to a common mechanism.[21] Expanding upon on the aforementioned deafferentation theory, Dr. Rabins proposed that sensory interruption in afferent cells and the loss of sensory end organs are quickly followed by hypersensitivity, and then expansion or relocation of the corresponding cortical receptive fields.[21] Hallucinations most likely result from spontaneous discharge of cells in the altered, newly innervated receptive fields.[14,21]

A type of selective deafferentation may be responsible for the

Relationship of CBS Hallucinations to the Visual Pathways

Hallucination Cluster	Visual Stream	Projection
Landscapes; small, costumed figures; vehicles; trees; and birds	Ventral	Inferior temporal cortex
Grotesque, disembodied, distorted, faces with prominent eyes	Unnamed	Superior temporal sulcus (STS)
Visual preservation; palinopsia	Dorsal	Parietal cortex

colored CBS hallucinations associated with macular degeneration. Following data interruption from the highly concentrated macular cones, there is hyperexcitablity of the color area in the ventral pathway that reduces inhibition and expression of colorful hallucinations.

Interestingly, many studies indicate a high incidence of hallucinations in people who live alone.[1] Because this lifestyle is a type of social sensory deprivation, deafferentation may play a role in the generation of these images. Additional support for deafferentaion is the reported elimination of CBS hallucinations following instances when visual acuity was, optically or medically, improved. Hallucinations attributed to macular degeneration were markedly reduced after photocoagulation therapy.[22]

Risk Factors

As might be expected, the greatest risk factor for these hallucinations is any severe, bilateral reduction in visual acuity that is consistent with the deafferentation theory. However, one study indicated that reduced contrast sensitivity is a better predictor of hallucination risk than acuity loss.[7]

Regardless, the high concentration of cortical input that corresponds to the macula accounts for visual hallucinations when a macular pathology degrades these afferent signals, consequently eliminating the normal inhibition and censorship of the visual association areas.[23]

While visual impairment can arise from disorders anywhere along the visual pathway, bilateral macular degeneration is most closely associated with the development of CBS. This is no surprise, because macular degeneration is the most prevalent cause of severe vision loss in the western world.

Other ophthalmic conditions associated with hallucinations are cataract, glaucoma, retinal detachment, enucleation, optic neuritis secondary to multiple sclerosis, cortical blindness and macular holes.

Non-ophthalmic causes are metabolic, infectious or vascular. They include diabetes mellitus with uncompromised vision, HIV with manifestations of cytomegalovirus retinitis and vertebral basilar insufficiency.[1]

Finally, there have been isolated reports of CBS in patients who have undergone peripheral iridotomies and intravitreal bevacizumab therapy for macular degeneration.[1]

These hallucinations occur more frequently in the context of sudden visual loss and are never found in the congenitally blind. The severity of acuity loss is more significant than its underlying etiology when assessing risk for CBS. Patients are at risk for CBS when the acuity in the better eye falls below 20/60.

According to several reports, improvement of acuity secondary to cataract extraction or photocoagulation decreases or eliminates these visual phenomena.[16] Furthermore, a study published in 2008 showed that low vision rehabilitation was associated with a 27% reduction in hallucinations in CBS patients.[24]

Visual Streams and Cerebral Specialization

There are three cerebral pathways that transmit cortically processed signals to specific areas of the brain. Each stream conveys information with unique visual attributes, and projects them to specialized regions.

One study investigated various hallucinations found in 34 CBS patients. The researchers grouped 12 common types of hallucinations into three symptom clusters and proposed that hallucinations in each cluster were commonly linked to increased activity in specific regions of the brain (*see "Relationship of CBS Hallucinations to the Visual Pathways," above*).[25]

The ventral pathway, often referred to as the "what stream," transports visual information that originated in the ganglionic P cells. This stream presents the resulting cortically processed data to the inferior temporal cortex. This pathway features signals that are associated with color perception, luminance, stereopsis and pattern recognition. Functional MRI studies have shown that the ventral temporal lobe is specialized for complex features of objects and landscapes.[25] CBS hallucinations consisting of scenery, vehicles, trees, and figures with hats and

costumes correspond to the functional specialization of this region. It is likely that the increased activity in the ventral stream's projections is responsible for these types of hallucinations.[25]

The dorsal stream, commonly referred to as the "where pathway," transports signals that originate in the ganglionic M cells, which are eventually processed in the striate and extrastriate cortices. Data is then projected to the posterior parietal cortex by this stream and is associated with object location, movement and the stabilization of images during saccades. Palinopsia, a disorder involving preservation of visual images after the objects are no longer in the field of view, is linked to disorders of the parietal cortex.[1]

The third and final category of CBS hallucinations consists of grotesque faces with distorted and rearranged features, including oversized eyes and teeth. Of the four regions in the brain that selectively respond to different facial stimuli, these images correspond to overactivity in the superior temporal sulcus (STS).[26] This area is responsible for processing variable aspects of the human face, include expressive features around the eyes. The STS is located between the dorsal and ventral pathways, suggesting a causative link.[26]

Further evidence linking hallucinatory syndromes and visual streams comes from a study that documented an association of dorsal projections with the peripheral visual field as well as a relationship between ventral projections and the central visual field.[26] This finding corresponds well with the cluster of hallucinations that is generated by each stream. Palinopsia, for example, is an illusion that is exclusive to the peripheral field, whereas hallucinations of figures and landscapes are found in the central field.[26]

Content and Characteristics

CBS-induced hallucinations frequently occur upon awakening, with the eyes open and the patient alert. Images appear suddenly and usually last several seconds.

Occasionally, however, some visions will persist for minutes to hours. They are exclusively visual, brilliant, sharply focused, often lack movement, and may merge or blend in with pre-hallucinogenic views. Saccadic eye movements, eyelid closure, and attempts to interact with the hallucination have been reported as effective methods of terminating CBS hallucinations.[1,17,27,28]

A latent period ranging from hours to days follows the onset of vision loss. Hallucinations tend to begin suddenly and last several months. There is general agreement that the CBS syndrome disappears when vision either improves or—more commonly—declines significantly.

Hallucinations associated with CBS can follow one of three courses:

- *The appearance of images may alternate from periods of hallucinatory activity and inactivity.*
- *They may last for days to months before completely vanishing.*
- *They may occur continuously with no remission.*

Insight and Response

CBS patients have full or partial insight and usually understand the inauthenticity of the images. However, this may not occur initially, because the images may genuinely complement the existing scene. Any conscious insight that develops may be intermittent.

Similarly to the development of insight, this neutral-to-positive response does not happen immediately. Geriatric patients who experience the sudden appearance and disappearance of images may fear for their mental wellness, and might be concerned that they are on the threshold of insanity.

Cognition

Currently, there is no consensus regarding the level of cognition in CBS. As noted earlier, Bonnet's documentation indicated that intact cognition is a requirement for the syndrome. Other researchers have proposed that visual hallucinations are an early sign of dementia.[29] They maintain that CBS occurs in the presence of reduced cognitive levels and visual loss.

The lack of distress shown by many hallucinators may indicate poor awareness of the potential gravity of these symptoms. Further, the combination of visual loss and early cognitive deficit may combine to facilitate the hallucinations of CBS.[29]

Differential

- ***Parkinson's disease.*** There are many similarities in the visual hallucinations associated with CBS and Parkinson's disease. They include insight and awareness, the involuntary nature of the images, and the occurrence of hallucinations when patients are alert with open eyes.

Characteristic differences are the clarity of CBS hallucinations compared to the reportedly blurred images of Parkinson's patients. Additionally, CBS is associated with highly colorful images that usually lack movement, unlike the hallucinations associated with Parkinson's.

- ***Psychosis.*** Visual hallucinations associated with psychosis and paranoia are multi-modal,

involving visual images combined with sounds. Insight is overwhelmingly poor, further differentiating visions from those associated with CBS and Parkinson's.

• ***Substance abuse.*** Hallucinations are also prominently associated with drug intoxication and withdrawal. Further, they are a potential adverse side effect of several medications, such as donezepil, tramadol, anti-depressants and quinolones, as well as the desired effect of hallucinogenic recreational drugs.

Treatment

Management of CBS includes a three-pronged, interventional approach that encompasses optics, medications and psychology. According to several reports, full or partial reversal of the vision loss that precipitated the hallucinations usually reduces or eliminates hallucinations.[30] This may be accomplished medically, surgically or through low vision rehabilitation.

While the hallucinations are benign by nature, many patients still feel disturbed and/or threatened. Pharmacologic treatment is controversial and reserved for this group of hallucinators. Antipsychotics, anticonvulsants and serotonin reuptake inhibitors have been used to help these patients. Specific medications include risperidone, valproate, clonazepam and olanzapine.[30] Gabapentin has been successfully used when other medications have failed to produce relief.[30]

Finally, the underlying fear of psychosis needs to be allayed. All CBS patients need reassurance that their symptoms are not an unexpected result of severe bilateral vision loss.

Many medical conditions are associated with visual hallucinations, and each entity possesses unique characteristics and distinctive features. Similarities do exist, however, and often result from a common, unified mechanism.

Hallucinations that occur secondary to strokes, migraines, intracranial lesions and cortical epilepsy ultimately are traceable to neuronal excitability and spontaneous discharge followed by cortically spreading depression. The aura of migraine is a function of spontaneous discharge and the ensuing headache results from cortical depression.

Sensory deprivation, deafferentation, denervation and release are all interconnected theories that explain the generation of hallucinations associated with sensory loss—specifically CBS. Visual phenomena associated with CBS arise from neuronal hyperexcitability and eventual spontaneous discharge. These hallucinations are unique, because they result from an expansion or relocation of cortical receptive fields.

The discrepancy between the number of patients who suffer from bilateral vision loss and the relatively few individuals who present with hallucinations has been a longstanding issue with the deafferentaion theory. Dr. Rabins tried to resolve this by postulating that CBS hallucinations occur following visual loss only when there was a prior injury or insult that altered the receptive fields.

Within the last 30 years, CBS has transitioned from an esoteric syndrome found mainly in the psychiatric literature to a slightly better known ophthalmological entity. Patients who experience hallucinations caused by CBS, stroke, migraine, Parkinson's disease and drugs can and often do present to an optometrist. So, it is beneficial for us to understand the potential cause and characteristic presentation of such phantom imagery. Because CBS is a diagnosis of exclusion, hallucinating patients who are suspected of suffering from CBS should be evaluated to rule out other neurological causes, including intracranial pathology. ■

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OSC QUIZ

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1. Visual hallucinations may be associated with which condition?
a. Migraines.
b. Parkinson's disease.
c. Stroke.
d. All of the above.

2. Complex visual hallucinations include:
a. Spots of light.
b. Simple patterns.
c. Lines.
d. Vivid scenery.

3. Visual hallucinations occurring in normal patients are:
a. Associated with excessive daytime sleep and narcolepsy.
b. Referred to as "hypnogogic" hallucinations.
c. Seen in patients with abnormal REM sleep patterns.
d. All of the above.

4. Hallucinations associated with posterior cerebral artery infarctions are:
a. Limited to the visual modality.
b. Have a latency of several weeks.
c. Occur in the hemianopic field.
d. All of the above.

5. Which statement is true?
a. Prevalence of migraine headache is 25%.
b. Auras are found in 90% of migraine sufferers.
c. A classic aura consists of zig-zag lines (fortification spectra).
d. Migrainous aura is preceded by scotoma or hemianopsia.

6. Which statement about migrainous auras is true?
a. They develop rapidly.
b. They usually persist for more than three hours.
c. They must be differentiated from visual phenomena secondary to intracranial pathology.
d. They occur in 50% of all migraine patients.

7. Which finding is associated with the aura of migraine?
a. Glial depolarization.
b. Neuronal hyperexcitability.
c. Spontaneous neuronal discharge.
d. All of the above.

8. Neuronal excitability precedes hallucinations associated with:
a. Migraines.
b. Charles Bonnet Syndrome (CBS).
c. Both a and b.
d. None of the above.

9. What is the most common neurological disorder associated with complex visual hallucinations?
a. Posterior cerebral artery infarction.
b. Rostral brainstem lesions.
c. Parkinson's disease.
d. Epilepsy.

10. Which statement is true regarding visual hallucinations associated with Parkinson's disease?
a. They are simple.
b. They are similar to peduncular hallucinosis.
c. They occur at the begining of the day.
d. They unrelated to the severity of the underlying disease.

11. Complex hallucinations occur in up to what percentage of CBS patients who experience the severe bilateral vision loss?
a. 5%.
b. 15%.
c. 25%.
d. 45%.

12. Simple visual hallucinations are more frequently found in patients with which condition?
a. CBS.
b. Posterior cerebral artery infarction.
c. Parkinson's disease.
d. All of the above.

13. CBS yields a constellation of signs/symptoms that generally includes:
a. Severe bilateral vision loss.
b. Macular degeneration as a frequent etiology of visual acuity loss.
c. Both complex and simple visual hallucinations.
d. All of the above.

14. Hallucinations secondary to CBS may be caused by:
a. Alterations in cortical receptive fields.
b. Degraded cortical input.
c. Denervation.
d. All of the above.

OSC QUIZ

15. The deafferentation theory:
a. Is based upon the nervous systems' response to poor quality input and denervation.
b. Postulates that CBS-induced hallucinations are caused by neuronal hyperexcitabililty and spontaneous discharge.
c. Explains the occurrence of the phantom limb syndrome.
d. All of the above.

16. The vividly colored hallucinations of CBS associated with macular degeneration are due to:
a. A high concentration of macular cones.
b. Selective deafferentation.
c. Retinal peripheral neovascularization.
d. Both a and b.

17. Which condition is NOT commonly associated with CBS?
a. Dense cataracts.
b. Fuchs' dystrophy.
c. Retinal detachments.
d. Glaucoma.

18. CBS-induced hallucinations are:
a. Exclusively visual and often brilliant.
b. Poorly focused.
c. Most frequently appear black and white.
d. Rarely involve images of people.

19. Patients with either CBS or Parkinson's disease often:
a. Demonstrate awareness and insight about the inauthenticity of hallucinated imagery.
b. Notice hallucinations during pre-dawn hours.
c. Experience exclusively simple visual hallucinations.
d. Notice hallucinations when their eyes are closed.

20. Which drug may be used to treat patients with CBS who have responded poorly to other medications:
a. Valproate.
b. Olanzapine.
c. Gabapentin.
d. Risperidone.

Examination Answer Sheet

Valid for credit through March 1, 2015

This exam can be taken online at www.revoptom.com. Upon passing the exam, you can view your results immediately. You can also view your test history at any time from the website.

An Overview of Visual Hallucinations

Directions: Select one answer for each question in the exam and completely darken the appropriate circle. A minimum score of 70% is required to earn credit.

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Schedule

Thursday, July 19, 2012

2:00pm – 4:00pm	Visit Sponsors & Registration
4:00pm – 6:15pm	CE Courses
6:15pm – 7:15pm	Welcome Reception

Friday, July 20, 2012

6:30am – 7:00am	Breakfast with Sponsors
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Saturday, July 21, 2012

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A Wound That Won't Heal

When treating diabetic patients, you may need to pull out all the stops to put an end to recurrent corneal erosions. **Edited by Joseph P. Shovlin, O.D.**

Q What treatment approaches can you recommend for a diabetic patient with persistent recurrent corneal erosion (RCE)—despite scraping, repeated bandage lenses and stromal puncture?

A Because their corneas heal more slowly and sometimes in an aberrant fashion, patients with diabetes are more prone to RCE and other complications. RCE is thought to be more common among people with diabetes due to deposition of advanced glycation end products (AGEs), a kind of "glucose cement" on the hemidesmosomes that anchor the basal corneal epithelium to Bowman's layer. These deposits make the anchor points less elastic, so even minor trauma or rubbing of the eyes can result in epithelial sloughing.

Before initiating any treatment, W. Lee Ball, O.D., associate director of medical affairs at Johnson & Johnson Vision Care Institute, Inc., says it's best to talk with patients about their level of diabetes control. "Ask them what their glycosylated hemoglobin levels are and when they last had them checked—ideally, they should be as close to 6.5% as possible without causing episodes of hypoglycemia," he says. "Wound healing is slow to begin with in patients with diabetes, but that's exacerbated significantly when it's not well controlled, so you want to address that first." Dr. Ball also stresses the importance of pinpointing what caused the original insult to exclude the possibility of an underlying epithelium basement membrane disease.

A. Paul Chous, M.A., O.D., also believes diabetes control should be top priority. "My first strategy is to reduce blood glucose levels to limit further AGE formation (HbA1c target < 7% or at least 10% lower than current level)," says Dr. Chous, who practices in Tacoma, Wash., where he specializes in diabetes eye care and education. "I would also add an AGE inhibitor like benfotiamine, a lipophilic analog of vitamin B_1 that has been shown to reduce AGEs in animals and humans with diabetes." He recommends 250mg of benfotiamine b.i.d. with meals.

Dr. Chous has had success with a combination of FreshKote (Focus Laboratories) t.i.d. to q.i.d. to increase oncotic pressure; oral doxycycline 100mg q.d.; and Lotemax (loteprednol 0.5%, Bausch + Lomb) q.i.d. to inhibit matrix metalloproteinase (MMP)-9, which is known to contribute to epithelial breakdown in recurrent corneal erosion. Studies have found this combination approach effective in patients who have failed other forms of treatment.[1]

"Because AGEs are metabolized at a very slow pace, I would continue this regimen for six months in recalcitrant cases, backing off on the doxycycline and steroid once recurrences are stabilized," he says.

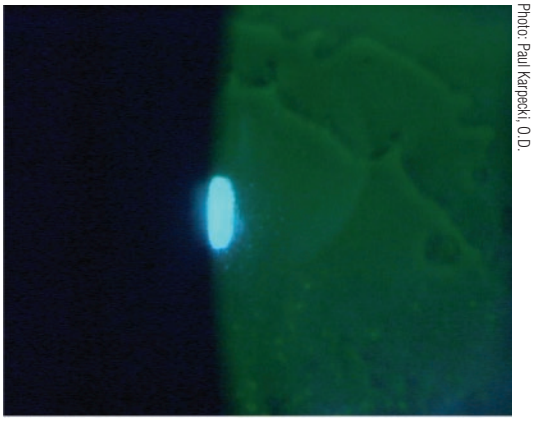

Photo: Paul Karpecki, O.D.

Presentation of reccurent corneal erosion.

You'll want to follow up weekly to bi-monthly, performing a visual inspection with fluorescein or lissamine green to get an overall idea of the progress the cornea is making, until re-epithelialization occurs.

"Once you've gotten the epithelium to lay down, cyclosporine (Restasis, Allergan) can be very useful in slowing down the inflammatory cascade and has the additional benefit of getting the eye to produce more of its own tears," Dr. Ball says. "However, that takes time to work so it's more of a long-term solution after you've gotten the eye to re-epithelialize, in order to mitigate or prevent future corneal erosions."

If all else fails, you might want to refer the patient to a corneal specialist for consideration of alcohol debridement or excimer laser phototherapeutic keratectomy. ■

1. Wang L, Tsang H, Coroneo M. Treatment of recurrent corneal erosion syndrome using the combination of oral doxycycline and topical corticosteroid. Clin Experiment Ophthalmol. 2008 Jan-Feb;36(1):8-12.

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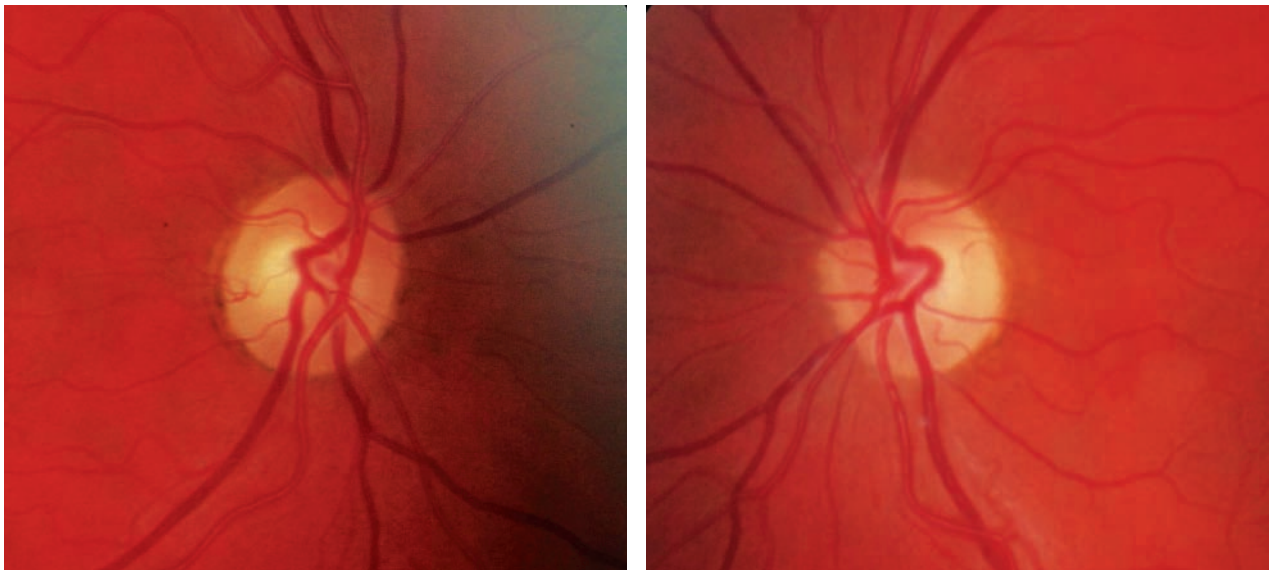
MS and the Eye (Part 2)

Because MS commonly affects the ocular structure, O.D.s play an important role in diagnosis and management. **By Carlo J. Pelino, O.D., and Joseph J. Pizzimenti, O.D.**



Disc photos of a 58-year-old white female with long-standing multiple sclerosis. Note areas of optic nerve atrophy and nerve fiber layer thinning.

Multiple sclerosis (MS) is a chronic, recurrent disease characterized by disseminated patches of demyelination. Over time, patients manifest episodic neurologic dysfunction due to inflammation in different regions of the central nervous system.[1] The most commonly affected areas are the brain, spinal cord and optic nerves—therefore, the optometrist may be the first physician to whom an MS patient presents.

Common neurologic symptoms of MS include sensory disturbances, motor weakness and trigeminal neuralgia. Patients may experience spontaneous and movement-induced muscle spasms, sensory problems (paresthesias and hypesthesia), ataxia, bladder dysfunction, constipation, cognitive dysfunction, depression, fatigue, sexual dysfunction, facial weakness, vertigo and hearing loss.[2]

In the first part of this two-part column (*"MS and the Eye (Part 1)," January 2012*), we presented an overview of demyelinating disease, with a focus on MS. In Part 2, we discuss the classification, diagnosis and management of MS.

Common Neuro-ophthalmic Symptoms

Common neuro-ophthalmologic symptoms in MS are unilateral vision loss due to optic neuritis, oscillopsia due to nystagmus, and diplopia due to internuclear ophthalmoplegia (INO) or cranial neuropathy. The occurrence of bilateral INO is considered to be highly suggestive of MS, especially in young patients. A new-onset acquired pendular nystagmus is relatively common, but other forms of nystagmus may occur as well, depending on the location of the demyelinating lesion.

Combinations of deficits, including horizontal or vertical gaze palsies, wall-eyed bilateral INO or wall-eyed monocular INO, or paralytic pontine exotropia (the "one-and-a-half syndrome"), may also occur in MS.[3] (*See "Common Ophthalmic Manifestations of MS," below.*)

Classification System

MS has four clinical types:[2-4]

• *Relapsing/remitting (RRMS)* accounts for 85% of MS cases at onset. Attacks evolve over days to

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INDICATIONS AND USAGE:
TRAVATAN Z® Solution is a prostaglandin analog indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION:
One drop in the affected eye(s) once daily in the evening.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS:
Pigmentation: Pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation likely to be permanent.

Eyelash Changes: Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible.

ADVERSE REACTIONS:
Most common adverse reaction (30% to 50%) is conjunctival hyperemia.

USE IN SPECIFIC POPULATIONS:
Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

Before prescribing TRAVATAN Z® Ophthalmic Solution, please read the brief summary of prescribing information.

References:
1. Lewis RA, Katz GJ, Weiss MJ, et al. Travoprost 0.004% with and without benzalkonium chloride: a comparison of safety and efficacy. *J Glaucoma*. 2007;16(1):98-103. **2.** Gross RL, Peace JH, Smith SE, et al. Duration of IOP reduction with travoprost BAK-free solution. *J Glaucoma*. 2008;17(3):217-222.

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Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

TRAVATAN Z® (travoprost ophthalmic solution) 0.004% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

2 DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) once daily in the evening. TRAVATAN Z® (travoprost ophthalmic solution) should not be administered more than once daily since it has been shown that more frequent administration of prostaglandin analogs may decrease the intraocular pressure lowering effect.

Reduction of the intraocular pressure starts approximately 2 hours after the first administration with maximum effect reached after 12 hours.

TRAVATAN Z® may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

3 DOSAGE FORMS AND STRENGTHS

Ophthalmic solution containing travoprost 0.04 mg/mL.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Pigmentation

Travoprost ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as travoprost is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of travoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with TRAVATAN Z® (travoprost ophthalmic solution) 0.004% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

5.2 Eyelash Changes

TRAVATAN Z® may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

5.3 Intraocular Inflammation

TRAVATAN Z® should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

5.4 Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with travoprost ophthalmic solution. TRAVATAN Z® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

5.5 Angle-closure, Inflammatory or Neovascular Glaucoma

TRAVATAN Z® has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.

5.6 Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

5.7 Use with Contact Lenses

Contact lenses should be removed prior to instillation of TRAVATAN Z® and may be reinserted 15 minutes following its administration.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The most common adverse reaction observed in controlled clinical studies with TRAVATAN® (travoprost ophthalmic solution) 0.004% and TRAVATAN Z® (travoprost ophthalmic solution) 0.004% was ocular hyperemia which was reported in 30 to 50% of patients. Up to 3% of patients discontinued therapy due to conjunctival hyperemia. Ocular adverse reactions reported at an incidence of 5 to 10% in these clinical studies included decreased visual acuity, eye discomfort, foreign body sensation, pain and pruritus.

Ocular adverse reactions reported at an incidence of 1 to 4% in clinical studies with TRAVATAN® or TRAVATAN Z® included abnormal vision, blepharitis, blurred vision, cataract, conjunctivitis, corneal staining, dry eye, iris discoloration, keratitis, lid margin crusting, ocular inflammation, photophobia, subconjunctival hemorrhage and tearing.

Nonocular adverse reactions reported at an incidence of 1 to 5% in these clinical studies were allergy, angina pectoris, anxiety, arthritis, back pain, bradycardia, bronchitis, chest pain, cold/flu syndrome, depression, dyspepsia, gastrointestinal disorder, headache, hypercholesterolemia, hypertension, hypotension, infection, pain, prostate disorder, sinusitis, urinary incontinence and urinary tract infections.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Teratogenic effects: Travoprost was teratogenic in rats, at an intravenous (IV) dose up to 10 mcg/kg/day (250 times the maximal recommended human ocular dose (MRHOD), evidenced by an increase in the incidence of skeletal malformations as well as external and visceral malformations, such as fused sternebrae, domed head and hydrocephaly. Travoprost was not teratogenic in rats at IV doses up to 3 mcg/kg/day (75 times the MRHOD), or in mice at subcutaneous doses up to 1 mcg/kg/day (25 times the MRHOD). Travoprost produced an increase in post-implantation losses and a decrease in fetal viability in rats at IV doses > 3 mcg/kg/day (75 times the MRHOD) and in mice at subcutaneous doses > 0.3 mcg/kg/day (7.5 times the MRHOD).

In the offspring of female rats that received travoprost subcutaneously from Day 7 of pregnancy to lactation Day 21 at doses of ≥ 0.12 mcg/kg/day (3 times the MRHOD), the incidence of postnatal mortality was increased, and neonatal body weight gain was decreased. Neonatal development was also affected, evidenced by delayed eye opening, pinna detachment and preputial separation, and by decreased motor activity.

There are no adequate and well-controlled studies of TRAVATAN Z® (travoprost ophthalmic solution) 0.004% administration in pregnant women. Because animal reproductive studies are not always predictive of human response, TRAVATAN Z® should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

A study in lactating rats demonstrated that radiolabeled travoprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRAVATAN Z® is administered to a nursing woman.

8.4 Pediatric Use

Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

8.5 Geriatric Use

No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

8.6 Hepatic and Renal Impairment

Travoprost ophthalmic solution 0.004% has been studied in patients with hepatic impairment and also in patients with renal impairment. No clinically relevant changes in hematology, blood chemistry, or urinalysis laboratory data were observed in these patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

TRAVATAN Z® (travoprost ophthalmic solution) 0.004% is a sterile, isotonic, buffered, preserved, aqueous solution of travoprost (0.04 mg/mL) supplied in Alcon's oval DROP-TAINER® package system.

TRAVATAN Z® is supplied as a 2.5 mL solution in a 4 mL and a 5 mL solution in a 7.5 mL natural polypropylene dispenser bottle with a natural polypropylene dropper tip and a turquoise polypropylene or high density polyethylene overcap. Tamper evidence is provided with a shrink band around the closure and neck area of the package.

2.5 mL fill	NDC 0065-0260-25
5 mL fill	NDC 0065-0260-05

Storage: Store at 2° - 25°C (36° - 77°F).

Rx Only

U.S. Patent Nos. 5,631,287; 5,889,052, 6,011,062; 6,235,781; 6,503,497; and 6,849,253

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TRV11503JAD

weeks, but there is usually complete recovery over the ensuing weeks to months. Between attacks, patients are neurologically stable.

• *Secondary progressive MS (SPMS)* begins as RRMS and then changes during the clinical course so that the patient experiences steady deterioration in function that isn't associated with acute attacks. SPMS produces a greater amount of fixed neurologic disability than RRMS.

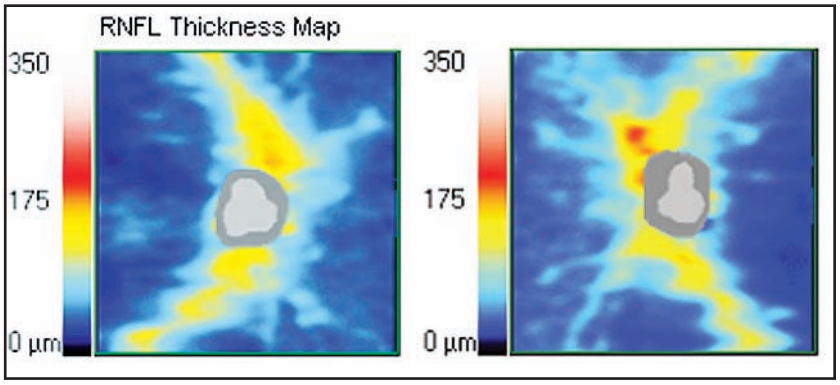
• *Primary progressive MS (PPMS)* patients do not experience attacks, only a steady decline from the disease onset.

• *Progressive relapsing MS (PRMS)* patients experience steady deterioration in their condition from the onset; however, as in SPMS, there are occasional attacks that overlap with the progressive course.

Establishing a Diagnosis

An MRI scan (T1 and T2) with fluid attenuated inversion recovery sequencing (FLAIR) and gadolinium infusion is the neuroimaging study of choice. MRI is excellent for identification of white-matter plaques, and is superior to CT scan for visualizing the posterior fossa and spinal cord. Plaque lesions may take on a spherical or ovoid configuration, and vary in size from 1mm or 2mm to several centimeters. Plaques are often situated at the ventricular margins, optic nerves and chiasm, corpus callosum, spinal cord, and throughout the brain stem and cerebellar peduncles.[2-4]

The cerebrospinal fluid (CSF) in patients with definite MS is abnormal in more than 90% of cases. The most common abnormalities are increased levels of immunoglobulin G (IgG), the elevation of the IgG/albumin index and the presence of oligoclonal IgG bands.[3] There are no definitive diagnostic tests for MS, so the disease remains a clinical diagnosis.[1-3] The McDonald criteria for diagnosing MS allows for the use of paraclinical data, which includes MRI and CSF studies.[5]



Advances in ophthalmic imaging with OCT have made it possible to quantify RNFL atrophy as a structural marker of axonal injury in the afferent visual pathway in patients with MS.

Advances in ophthalmic imaging with optical coherence tomography (OCT) have made it possible to quantify retinal nerve fiber layer (RNFL) atrophy as a structural marker of axonal injury in the afferent visual pathway in patients with MS. Studies have shown that OCT-measured RFNL values are reduced in patients with MS with and without a history of optic neuritis; however, RNFL atrophy tends to be greater in eyes affected by optic neuritis.[6]

Therapeutic Options and Considerations

There is no cure for MS. The early promotion of remyelination and preservation of oligodendrocytes remain important therapeutic goals.[1-3]

Therapy for MS can be divided into several categories: treatment of acute attacks as they occur; treatment with disease-modifying agents that reduce the biological activity of MS; and symptomatic therapy.[1]

High-dose, intravenous corticosteroids (methylprednisolone 500mg/d to 1,000mg/d for three to five days, followed by a course of oral prednisone beginning at a dose of 60mg/d to 80 mg/d and tapered over two weeks) are often used to treat acute exacerbations of MS. However, no evidence shows lasting improvement or alteration of prognosis with corticosteroid administration.

Other immunosuppressive and immunomodulating agents—Avonex (interferon beta-1a, Biogen Idec.), Rebif (interferon beta-1a, EMD Serono, Inc. and Pfizer Inc.), Betaseron (interferon beta-1b, Bayer Healthcare), Copaxone (Glatiramer, Teva) and Tysabri (natazilumab, Biogen Idec and Elan Pharmaceuticals, Inc.)—may be

Common Ophthalmic Manifestations of MS

- **Optic neuritis**—inflammation of optic nerve in one or both eyes, typically retrobulbar.
- **Nystagmus**—typically pendular, but upbeat, downbeat, convergence-retraction may also occur.
- **Internuclear ophthalmoplegia (INO)/bilateral INO**—adduction deficit of ipsilateral eye with horizontal gaze nystagmus in the contralateral abducting eye.
- **Cranial nerve palsies (III, VI)**

useful in long-term treatment.[1,3] Current research suggests that early diagnosis and therapy is critical.[3]

Mortality as a direct consequence of MS is uncommon. Death can occur during an acute MS attack; although this is a rare event. More commonly, death occurs as a complication of MS (e.g., pneumonia).[1]

Differential Diagnosis

It is important to note that neuromyelitis optica (NMO), another idiopathic inflammatory demyelinating disease of the central nervous system, also predominantly affects the optic nerves and spinal cord and should be highly considered as a differential diagnosis to MS. NMO antibodies (aquaporin-4 antibodies) can be routinely tested and have become a major diagnostic criteria for NMO. However, there is still some debate among the neuro-ophthalmology community if the aquaporin-4 antibodies should be routinely tested in patients with isolated optic neuritis.

Demyelinating disorders are characterized by inflammation and selective destruction of the central nervous system myelin.[1] Because MS is one of the most common acquired neurologic disorders in the United States, it is important for optometrists to be familiar with both its ocular and neurologic consequences so that they can make an accurate diagnosis and administer proper management.[2,3] ■

Who Gets MS?[7]

- MS is at least two to three times more common in women than men.
- Most people are diagnosed between the ages of 20 and 50; however, MS can appear in young children and teens as well as much older adults.
- MS occurs in most ethnic groups, including African-Americans, Asians and Hispanics/Latinos, but is more common in Caucasians of northern European ancestry.

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Protecting Tear Proteins to Maintain Their Natural Antimicrobial Function - Biotrue™ Multipurpose Solution

Chris Snyder, OD, MS, FAAO

The attraction and accumulation of tear film proteins onto contact lenses has historically been viewed negatively. This is because the presence of denatured protein deposits can result in reduced vision, discomfort and clinical complications for the contact lens wearer. But taking inspiration from the natural biology of the eye, there may be advantages to keeping certain beneficial tear proteins in their native conformation and biologically active against microorganisms.

Almost 500 proteins are naturally present in tear film.[1] A few, including lysozyme and lactoferrin, are present in high concentrations[2] and possess inherent antimicrobial properties.[3] With an appreciation of their antimicrobial properties in the healthy tear film, perhaps lens care products should maintain these proteins in their natural state rather than simply working to remove them from contact lenses.[4] Maintaining their native state ensures retention of antimicrobial properties and may help to promote ocular health.[4,5]

The bio-inspired formula of Biotrue, shown to deliver up to 20 hours of continuous moisture[6], mimics the eye through an intelligent approach to protein management. Biotrue lifts and dissolves denatured proteins, as do other solutions on the market, but in comparison with other solutions tested, Biotrue keeps more lysozyme from denaturing[7] – therefore keeping more lysozyme active than other tested solutions.[8] Preserving this protein in its native, active state allows it to maintain antimicrobial activity.

NEW RESEARCH CONFIRMS LYSOZYME PROVIDES ANTI-MICROBIAL BENEFITS

A recent study by Dobson et al[9] evaluated the antimicrobial activity of native proteins extracted from worn lenses with different treatment regimens (Biotrue manufactured **without** disinfectants vs. peroxide-based solution, Oxysept). Worn and unworn etafilicon A contact lenses were treated overnight with either neutralized peroxide-based solution or Biotrue multi purpose solution manufactured without disinfectants. Lysozyme extracted from worn lenses was assessed using standard methods by measuring its rapid lytic activity against *Micrococcus luteus*. Functional activity of extracted lens proteins was tested by challenging suspensions of *Pseudomonas aeruginosa* and *Staphylococcus aureus* overnight, and by assessing numbers of surviving organisms.

The **protein stabilization results** showed that Biotrue manufactured **without** disinfectants maintained 38% more active lysozyme with worn lenses than the peroxide-based solution tested (Fig 1). The **antimicrobial testing results** showed that proteins stabilized by Biotrue manufactured **without** disinfectants helped provide a 2-3 log reduction of *Pseudomonas aeruginosa* and *Staphylococcus aureus,* two bacteria commonly associated with microbial keratitis in contact lens wear. (Fig 2)

The bio-inspired formulation of Biotrue helps keep key beneficial proteins active, while also lifting and dissolving denatured proteins. Dobson's study[9] showed us that not only did Biotrue keep more lysozyme active, but that the active lysozyme extracted from worn etafilcon A contact lenses provided natural antimicrobial activity. The antimicrobial activity of this active lysozyme may contribute to the efficacy of the formulation's dual disinfectants. By designing a lens care solution that has characteristics similar to the eye, it is possible to offer patients continuous comfort without trading off disinfection efficacy.

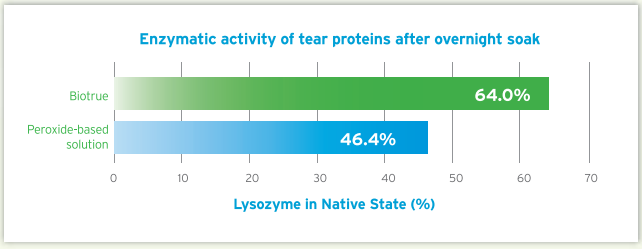

Figure 1: Protein stabilization results

*Biotrue manufactured **without** disinfectants maintained 38% more active lysozyme with worn lenses than the neutralized peroxide-based solution tested.*

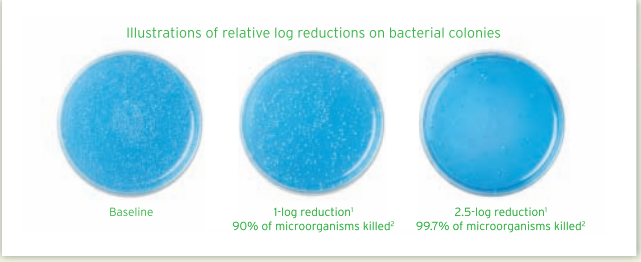

Figure 2: Antimicrobial testing results

*Proteins stabilized by Biotrue manufactured **without** disinfectants helped provide a 2-3 log reduction of Pseudomonas aeruginosa and Staphylococcus aureus.*

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A 'Grizzly' Presentation

This patient exhibited multiple pigmented lesions in both maculae. Is this indicative of a very serious underlying condition? **By Mark T. Dunbar, O.D.**

A 55-year-old black male presented with complaints of blurred vision at both distance and near. He reported that he only wore +2.00D over-the-counter reading glasses. The patient said that the glasses helped, but he still struggled to see.

His medical history was significant for HIV, which was diagnosed in 1992. Additionally, he reported hypertension and borderline high cholesterol. He did not know his CD4 number or his viral load, but indicated that he saw his doctor every three months. He took several medications, including Isentres (raltegravir, Merck), Prezista (darunavir, Janssen Therapeutics), Norvir (ritonavir, Abbott), PhenaTrim (weight loss supplement), acyclovir and lisinopril. He reported no known allergies.

On examination, his uncorrected visual acuity measured 20/200 O.D. and 20/100 O.S. With hyperopic correction, he was able to see 20/20 O.U. Confrontation visual fields were full to careful finger counting O.U. His pupils were equally round and reactive to light, with no afferent defect. Ocular motility testing was normal. The anterior segment examination was unremarkable. His intraocular pressure measured 13mm Hg O.U.

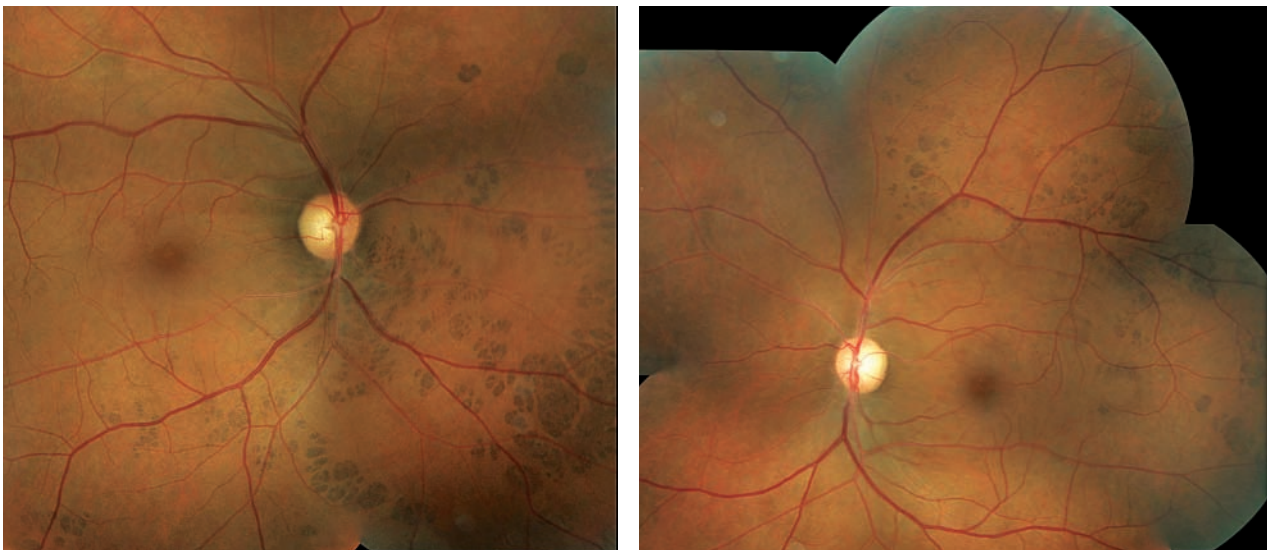
Dilated fundus exam showed clear vitreous without cells, as well as moderate-sized cups with good rim coloration and perfusion O.U. The vessels were of normal caliber and the maculae appeared normal. We noted multiple, peculiar lesions in each eye (*figures 1 and 2*). Additionally, we performed fundus autofluorescence (*figures 3 and 4*).

Take the Retina Quiz

1. What are the peculiar fundus lesions seen in both eyes?
   a. Choroidal nevi.
   b. Congenital hypertrophy of the retinal pigment epithelium (CHRPE).
   c. Infiltrative metastatic carcinoma.
   d. Primary malignant melanoma.

2. What is the significance of these lesions?
   a. There is no significance.
   b. Diagnostic for metastatic disease.
   c. Diagnostic for primary malignancy.
   d. Marker for intestinal malignancy.

3. What is the correct diagnosis?
   a. Multiple choroidal nevi.
   b. Bear tracks.
   c. Multiple CHRPE formation.



1, 2. Fundus photographs of our patient (O.D. left, O.S. right). Note the peculiar lesions scattered throughout the retinae.

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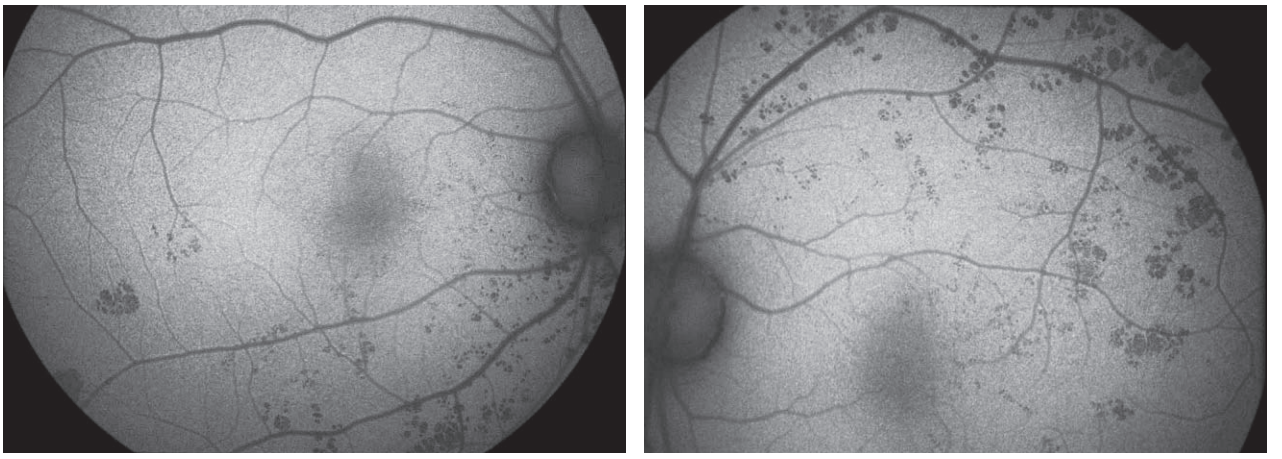

3, 4. Fundus autofluorescence reveals the presence of multiple pigmented lesions (O.D. left, O.S. right).

d. Gardner's syndrome.

4. How should this patient be managed?
a. Observation.
b. Plaque radiotherapy.
c. Referral for intestinal malignancy.
d. Enucleation.

For answers, go to page 130.

Discussion

The multiple lesions seen in both eyes represent a form of CHRPE. A typical CHRPE is a solitary, round, flat, well demarcated, hyperpigmented lesion that is present at birth.[1,2] Its color can vary from dark brown or black to gray, and lacunae can be present within the lesion.

CHRPE are benign lesions that are usually discovered as an incidental finding during a routine eye exam. However, there are variations in how CHRPE may present.

One particularly interesting CHRPE variation presents as clusters or groups of lesions, as seen in our patient. In fact, if you use a little imagination, you almost get the impression that the pigmented lesions look like the paw prints of an animal that has been walking around the retina. For that reason, these lesions have been referred to as "bear tracks."

Bear tracks are congenital anomalies that are characterized by small, sharply circumscribed, variably sized, pigment spots. They are often grouped in one sector of the fundus. In our patient, they were predominantly located in the nasal retina, inferiorly in the right eye and superiorly in the left. The bear tracks are significantly more apparent on fundus autofluorescence, where the hyperpigmentation causes evident blockages.

There has been some debate regarding the differences between CHRPE and bear tracks, because both presentations have a similar histopathology. In fact, it has been suggested that CHRPE and bear tracks are different expressions of the same condition.[2] However, there are ultrastructural differences between the two entities. For instance, bear tracks are more elliptical in shape than CHRPE. In addition, when examined under electron microscopy, hypertrophy and hyperplasia of the RPE cells is not a significant feature in patients with bear tracks.[2]

The presence of multiple CHRPE lesions in both eyes should raise a concern for Gardner's syndrome. Gardner's syndrome, also known as familial colorectal polyposis, is an autosomal dominant disease that is characterized by adenomatous polyposis of the large and small intestines, hamartomas of the skeleton and various soft tissue tumefactions.

The risk for intestinal malignancy in adults with Gardner's syndrome is virtually 100%.[1,3] However, the shape of the CHRPE lesions seen in these patients is uniquely different than what is seen in patients with either classic CHRPE formation or bear tracks. More specifically, such lesions are not round like most CHRPE, but more oval—almost exhibiting a football shape.[1]

We were confident that our patient had nothing more than classic bear tracks. In addition, he had no history of familial adenomatous polyposis or any other colon problems. We explained the findings to our patient, gave him a prescription for glasses, and asked him to return annually. ■

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A Generic Prostaglandin

What are the implications of prescribing generic latanoprost?

By Joseph W. Sowka, O.D., and Alan G. Kabat, O.D.

We would like to discuss some clinical scenarios that are likely taking place across the country today.

The first involves a 63-year-old man with primary open-angle glaucoma (POAG) who uses several topical mediations to control his intraocular pressure (IOP). He calls one day concerned that the pharmacy has mistakenly given him the wrong medication. He went to refill his Xalatan prescription but was surprised when he got home and found that he had been given a bottle of latanoprost.

The second patient is a 58-year-old woman with POAG who has been doing very well with Travatan Z (travoprost, Alcon). However, when the patient goes to her pharmacy, she is informed that her insurance no longer covers a branded prostaglandin analog (PGA). Instead, the pharmacist informs her that she has the option to either pay full price out of pocket for Travatan Z or ask her doctor if she could be prescribed generic latanoprost. We can all probably guess which option she will choose.

The third patient is a 69-year-old woman with POAG who uses multiple medications and is uninsured. She needs a PGA as part of her therapy, but confesses that Lumigan (bimatoprost, Allergan) has become prohibitively expensive along with her other medications. So, she asks if there is a cheaper generic alternative.

The factor common to all three: the advent of a generic PGA has come into their lives in one way or another. Is this a good thing?

As doctors treating patients, we like to make clinical decisions based upon what we believe is best for patients without being unduly influenced by external factors. However, that may not be realistic.

We all face issues with insurance companies' formulary coverage of medications, as well as patients' inability to afford them. Insurance companies and pharmacies operate as businesses and need to be profitable.

When a generic medication becomes available, there is financial pressure to use the generic version. Of course, as health care providers, we can fill out forms requesting exemptions that enable the patient to receive a branded medication.

Unfortunately, despite the best intentions and explanations, our requests usually are met with a standard denial. Thus, the patient either uses the generic version or, less frequently, pays full price for a branded medication.

But, is the use of a generic medication a bad thing for patients' health? What has the advent of a generic PGA done for glaucoma management? These are some of the issues that we will explore in this month's column.

Are Generic Medications 'Inferior?'

There exists a perception that generic medications are somehow inferior to branded medications. In some cases, this perception is true. For example, one study indicated that only 0% to 6% of generic prednisolone acetate 1% samples were within 10% of the intended concentration, depending upon handing methods.[1] (It is important to note that Pred Forte [prednisolone acetate, Allergan] performed much better in this study.[1]) Additionally, generic diclofenac sodium was shown to cause corneal melts more often than branded Voltaren (diclofenac, Novartis).[2,3]

Aside from such issues, patients have been successfully using generic medications—both systemically and topically—for years with no such ill effects. A case in point would be topical beta blockers, which are nearly all generic now.

While generic medications can work well, there is always some initial doubt about safety, efficacy and tolerability. Often, these doubts can be erased following effective use over time. Still, generics sometimes tend to be perceived as inferior. But, much of the initial doubt comes from doctors not understanding what goes into the manufacture of generic medications.

Branded and generic medications are not identical. In terms

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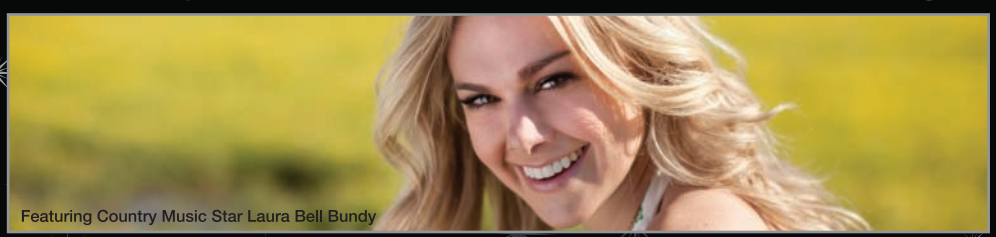

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Pricing Programs for Premium PGAs

Naturally, when a generic PGA alternative becomes available, there is concern that patients may be directed away from branded PGAs—either due to insurance or cost considerations. However, manufacturers of the branded PGAs so strongly believe in their products that they have developed programs to ensure that their medications remain a viable option for patients.

- Alcon has developed the Openings Program for Travatan Z. The patient receives a card which, when presented to a pharmacy, reduces his or her cost to no more than $25.00 per refill of Travatan Z. And just recently, Alcon added an option to purchase a 90-day supply of Travatan Z for $50.00. These offers apply to patients with no insurance as well as those with private insurance, where Travatan Z is at an elevated tier with a higher co-pay. Details about the program and patient co-pay cards may be obtained at: www.travatanz.com/openings/.
- A comparable program for Lumigan is available through Allergan. Known as the Lumigan 365 program, this plan provides a similar cost savings for the patient. The Lumigan 0.01% co-pay card allows patients to pay no more than $10 per prescription for up to one year. These cards are available from representatives of the company. Additionally, coupons and educational materials may be obtained for patients at http://lumigan.com/.

of the specific formulation, both brand and generic medications must include the same active ingredients in the same concentration and route of administration.

Beyond that, there can be differences in the inactive ingredients and preservatives. Generic medications must demonstrate the same bioequivalence as the branded product. Logically, if the blood concentration of the active ingredient is the same as that of the branded drug, a generic medication should have the same therapeutic effect—thus not requiring testing of clinical effectiveness.

Additionally, generic solutions do not have to undergo any further FDA testing as long as the active and inactive ingredients remain the same. In a solution where active and inactive ingredients are dissolved, there is no reasonable explanation for a generic and branded medication to perform differently. However, this is not true for suspensions, emulsions and ointments, where particle size can influence efficacy. In these cases, comparative studies are required.

Because manufacturers are not required to release an exact composite of all of the inactive ingredients, generic medications typically are created through reverse engineering. Thus, there often will be subtle differences in each recipe from each manufacturer in terms of inactive ingredients. This may cause the patient to experience a different feeling when using a generic medication.

Further, because pharmacies typically receive their inventory shipments from different manufacturers, it is possible for a patient to get generic latanoprost made by one company and then receive a refill that is manufactured by a different company—even when using the same pharmacy each time. And, due to small variations in inactive ingredients, patients may experience different sensations and tolerability.

Also, it is important to note that some of the success of branded Xalatan comes from the uniform drop size discharged by the bottle. Generic latanoprost, however, features a bottle that looks and acts differently. This may be confusing to patients. The bottle may have a different feel and the drop size may vary, affecting the amount of medication dispensed. Further, the plastic that the bottle is composed of may absorb medication or even affect medication degradation over time. These are all differences that are unrelated to the medication concentration in the generic version.

Finally, and most importantly for some patients, the biggest difference is cost.

Experience Thus Far

Of course, the most important factor in the success or failure of any generic medication is the test of time. You want to learn whether patients experience similar IOP control on the medication, and if they tolerate the medication as well or better.

At this point, we have seen no clinical differences in efficacy between branded Xalatan and generic latanoprost. Any IOP variations that we have documented easily could be reflected by diurnal fluctuation, patient adherence or disease progression.

Keep in mind, however, that determining whether the IOP-lowering ability of generic latanoprost is the same as branded Xalatan is very challenging. What is more easily ascertained is how well the patient tolerates the medication (e.g., if the particular blend of inactive ingredients was not well tolerated, patients likely would complain). To date, we have not seen this as an issue in any significant way. Most interestingly, we also haven't seen much difference in cost either.

In southern Florida, it appears that generic latanoprost is only moderately less expensive than branded Xalatan as reported by our patients. We have heard reports and rumors of generic

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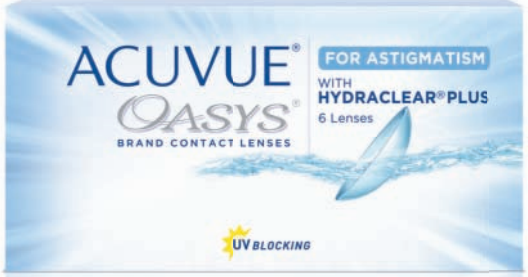

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latanoprost costing as little as $8.00 in some pharmacies in our area—but at this point, it remains an urban legend. Over time, as more manufacturers produce their versions of generic latanoprost, this may alter costs in the patients' favor.

Generic Inspiration?

When evaluating the implications of using a generic PGA, it is important to look beyond cost. It can be said that generic latanoprost has stimulated the PGA industry overall. It was long known that Xalatan would lose patent protection and be manufactured generically. In advance, manufacturers of other branded PGAs looked at their formulations and sought changes.

For example, Travatan Z was developed as a BAK-free alternative to Travatan. This was done to help alleviate toxic effects of BAK and preserve the ocular surface health of patients. Additionally, Allergan released a new, lower concentration version of Lumigan in an effort to achieve the same IOP-lowering efficacy while trying to reduce the hyperemic effects.

So, it seems that the advent of a new generic "competitor" at least partially stimulates brand name manufacturers of already excellent medications to try to further improve their existing products.

Now that we have a generic PGA, it is clear that there will be an impact upon topical glaucoma management. If nothing else, the advent of generic latanoprost certainly gives patients and practitioners a possibly lower cost alternative. Don't forget, however, that the anticipated availability of generic latanoprost also has inspired the manufacturers of branded PGAs to continually look for ways to improve their existing products as well as develop innovative programs designed to keep the branded PGAs in patients' hands and eyes. ■

Drs. Sowka and Kabat are consultants for Alcon. They have no direct financial interest in any of the products mentioned.

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VEGF Trap-Eye is Safe, Effective

The latest approved treatment for wet AMD has shown promising results, and requires less frequent dosing than Lucentis. **By Diana L. Shechtman, O.D., and Paul M. Karpecki, O.D.**

A 72-year-old white female presented with complaints of visual distortion. She stated that, over the past month, "things seemed wavy" when viewed through her left eye. Additionally, she reported an acute vision loss in her left eye that occurred a few days prior.

Her best-corrected visual acuity was 20/30 O.D. and 20/100 O.S. Pupils, extraocular motilities and confrontation visual fields were all within normal limits.

Fundoscopic evaluation revealed areas of retinal atrophy as well as peripapillary atrophy O.U. We documented the presence of drusen in both maculae. Also, we observed a serosanguineous macular detachment in her left eye that was consistent with wet age-related macular degeneration.

What are the best available treatment options for this patient?

Established Anti-VEGF Options

AMD is a complex, multifactorial disease. A volumetric increase in vascular endothelial growth factor (VEGF) and other growth factors has been shown to be a predominant component in the angiogenesis and permeability of the disease.

For years, we had limited options for the treatment of wet AMD that merely slowed the progression of vision loss. The advent of anti-VEGF therapy revolutionized the treatment of AMD, halting disease progression, and even making visual restoration possible.

Both FDA-approved Lucentis (ranibizumab, Genentech/Roche) and off-label Avastin (bevacizumab, Genentech/Roche) have proven to be safe and effective treatment options for patients with wet AMD.[1-3] Recent clinical data also suggest similar efficacy between Avastin and Lucentis in the treatment of wet AMD.[3]

However, one of the main limitations of both drugs is the need for frequent re-treatment to maintain optimal vision during the course of the disease.[1,2,4] Indeed, this can create significant time and financial burdens for most patients.

VEGF Trap-Eye Gains Approval

Clinical research in the development of effective drugs for wet AMD focuses on both improving visual restoration and extending the duration of treatment. Additionally, it is important to note that the newest drugs for wet AMD have been developed to inhibit multiple growth factors.

Following positive results from multiple global clinical trials, Eylea (aflibercept, Regeneron Pharmaceuticals), also known as VEGF Trap-Eye, received FDA approval for the treatment of wet AMD on November 18, 2011.[5,6]

VEGF Trap-Eye has been proven to be a safe, effective and durable treatment for wet AMD that may be administered every other month following the initial three-month dosage.

The drug is classified as a "fusion protein" that acts like a receptor decoy; it exhibits a high-binding affinity to VEGF receptors 1 and 2 as well as placental growth factors.[5,6]

Clinical studies have shown that VEGF Trap-Eye has a highly binding affinity for its receptor as well as a slow degrading process that is associated with a longer duration of effect compared to conventional anti-VEGF therapy.[5,6]

The VIEW (VEGF Trap-Eye Investigation of Efficacy & Safety in Wet AMD) studies consisted of two clinical trials that evaluated the efficacy of VEGF Trap-Eye at variable dosing regimens vs. monthly 0.5mg Lucentis injections.

VIEW 1 evaluated 1,217 individuals from North America and Canada, and VIEW 2 included 1,240 individuals from Europe, Japan, Asia and Latin America.[5,6] Subjects were randomized into four subgroups in both trials: 0.5mg Lucentis per month, 0.5mg VEGF Trap-Eye per month, 2mg VEGF Trap-Eye per month and 2mg VEGF Trap-Eye every other month.

At one year follow-up, both studies showed that more than 90% of the subjects across all groups achieved the primary end goal—maintenance of vision (*see "VIEW 1 vs. VIEW 2 Data," page 113*). And, most importantly, the researchers documented minimal side effects (primarily localized adverse events) associated with the use of VEGF Trap-Eye.[5,6]

Today, AMD affects approximately 1.75 million Americans. This number is likely to double by 2020.[7] Fortunately, anti-VEGF therapy has dramatically improved the visual prognosis of patients with wet AMD. However, it is limited by the need for frequent follow up and re-treatment.

Emerging therapies, including VEGF Trap-Eye, show promise for visual restoration in wet AMD patients as well as decreased dosing intervals.

In addition, ongoing clinical studies currently are assessing the safety and effectiveness of VEGF Trap-Eye in the treatment of diabetic macular edema and macular edema associated with retinal vein occlusion.[8] ■

VIEW 1 vs. VIEW 2 Data[6,7]

	Lucentis (0.5mg q1M)	VEGF Trap-Eye (0.5mg q1M)	VEGF Trap-Eye (2mg q1M)	VEGF Trap-Eye (2mg q2M)
Percentage of patients who achieved maintenance of vision				
VIEW 1	94.4%	95.9%	95.1%	95.1%
VIEW 2	94.4%	96.3%	95.6%	95.6%
Mean improvement in vision (measured as average number of ETDRS letters gained)				
VIEW 1	8.1	6.9	10.9	7.9
VIEW 2	9.4	9.7	7.6	8.9

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Product Review

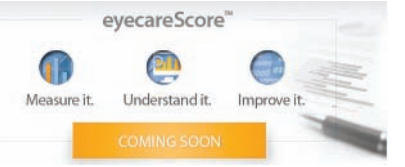
Practice Management

Power News

The Power Practice, a consulting firm founded by Gary Gerber, O.D., has brought back its popular paid newsletter, "Optometric Income," and rebranded it as "Power News." It was first launched in 2010 as "Optometric Income" and was one of the first-ever paid online practice building newsletters. Dr. Gerber believes three things set the monthly e-newsletter apart from others—the firm's large and successful client base are already using the strategies featured; the style is easy to read, digest and implement; and it's unconditionally guaranteed. "After a very successful year, we took some time off to regroup, rebrand, rethink and now re-launch the newsletter," he said. "We had a great response the first time out and know this one will be even better." For more information, visit www.powerpractice.com.

eyecareScore Survey

focalCenter will be launching its validated and standardized eyecareScore survey as an online subscription tool during the second quarter of 2012. It gives eye doctors, clinics, optical retailers and vision plans a standardized method for determining how their patients' experiences



Frames

MauiPure Line

This month, Maui Jim will debut its new MauiPure lens technology in a line of three sunglasses designed for active lifestyles—Olowalu, Mala and Nakalele. Olowalu is the smallest style in the collection and features a rectangular lens, while Mala has a slightly curved rectangular lens designed for average face sizes. Nakalele gives a nod to a rimless aviator in a larger style. Each 8-base rimless style features beta-titanium temples and adjustable Rabalon nose bridges for lightweight comfort.


Olowalu


Mala


Nakalele

Each style comes in three colors: black, rootbeer/copper or translucent grey. Three lens colors are available:

- Neutral grey offers the highest level of light reduction for bright, sunny days.
- HCL bronze enhances contrast in variable conditions.
- Maui HT (High Transmission) is the lens for when most lenses would be too dark.

For more information, visit www.mauijim.com.

Costa Sunglasses

Costa introduces three new sunglass styles—Caye, Las Olas and Peninsula—all available in Costa's patented

Frames


Caye


Las Olas


Peninsula

580P or 580G lenses, as well as Rx. Lens color options include gray, copper, amber, blue mirror, green mirror and silver mirror. The new styles range in price from $169 to $249, depending on customized lens choice. Prices for Rx sunglasses vary.

Caye's flexible yet sturdy stainless steel hinges and no-slip Hydrolite nose pads provide comfort, the company says, and the frames are available in tortoise, black and white. Las Olas features an oval shape nylon frame with Hydrolite nose pads and no-rust stainless steel hinges. It's available in tortoise, black and the new coral/white combination frame colors. A full-framed rectangular-shaped sunglass, Peninsula has wire core temples and stainless spring hinges, and is available in tortoise, black and black/coral. For more information, visit www.costadelmar.com.


sf101s


sf102sl


sf104sl


sf600s

Salvatore Ferragamo Collection

The Ferragamo Spring/Summer 2012 Sun Collection by Marchon aims to encompass unique and timeless styles that exemplify luxury. The Gancino and Vara—both iconic Ferragamo details commonly incorporated into the accessory collections—are elegantly placed on the frame. The Gancino is molded from polished metal and filled with colored enamel that highlights the timeless accent. Engraved with the Ferragamo logo, the Vara clasp is placed on the temples while dual zyls fill the enamel. The classic aviator is revitalized with frame fronts and the logo scripted on the lenses and end pieces wrapped in vivid color leather. For more information, visit www.marchon.com.


sf611sr


sf6175

Frames

Valentino Spring/Summer 2012 Collection

Vintage shapes, distinctive silhouettes and striking contrasts characterize the Valentino Eyewear Spring/Summer 2012 Collection by Marchon. It features iconic elements of Valentino style: lace, precise yet feminine lines, and studs.

- V611S: This vintage-style model, available in grey, brown and burgundy, features lace hidden on the bridge and temples.
- V606S: Tiny, lustrous studs line the top of the frame on this oversized square model.
- V102S: Available in black and combinations of black/grey, havana/brown, and havana/gold, this model has distinctive gems accentuated by contrasting materials.
- V603S: Available in black, gold havana, dark havana, ivory havana and red, this model features a subtle contrast between curved lines and sharp angles.

compare to their peers and measure up over time.

eyecareScore's benchmarks and metrics were developed using qualitative and quantitative testing to provide vital comparisons of key patient experiences, drivers of satisfaction and advocacy. For more information, visit www.focalcenter.com.

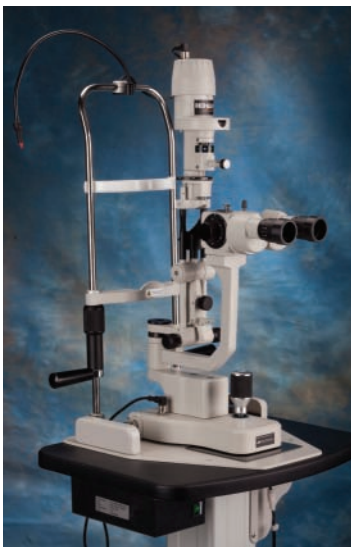
Dry Eye Therapy

Refresh Optive Advanced

Allergan, Inc. recently launched Refresh Optive Advanced, a new over-the-counter lipid-enhanced tear that offers the low blur and comfort of an aqueous tear. It features a comprehensive, triple-action formulation that works on all three layers of the tear film to reduce tear evaporation, hydrate and lubricate for dry eye symptom relief, the company says. Due to its optimized lipid content, Refresh Optive Advanced does not separate; it provides consistent stability, requiring no shaking prior to use. It's available at retail locations in 10mL bottles. For more information, visit www.refreshbrand.com.

Vision Assessment

iBEX Slit Lamp



The latest iBEX 5-Step LED Wave Slit Lamp delivers an industry-first 43mm field of view at standard 6x magnification, according to Trevi Technology. It allows for increased observation in less time, with significantly less joystick movement. Custom LED Illumination delivers bright, uniform illumination with full-spectrum wavelengths that have been synced to maximize anterior

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Scleral Lenses

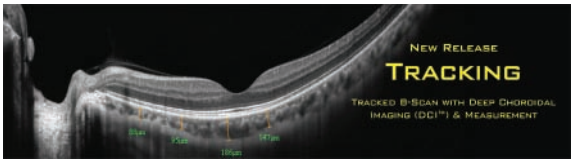
Maxim Plus and Comfort SL Plus

Acculens recently released two new scleral multifocals, Maxim Plus and Comfort SL Plus. Both multifocals incorporate center near add technology with aspheric zone blend. The Maxim Scleral lens is indicated for the management of corneal distortion and dry eyes. Maxim Plus will correct presbyopia while managing corneal distortion. Comfort SL Plus is indicated for normal corneas and is a great alternative to soft toric lenses. Both new multifocal designs are available in custom parameters and are manufactured in Boston XO2.

Maxim's 20-lens trial lens sets are available free of charge. No fitting set is needed for Comfort SL or Comfort SL Plus—simply call in K's, RX corneal diameter and pupil size to Acculens. For more information, call (800) 525-2470 or visit www.acculens.com.

and posterior viewing. Most importantly, the company says, heat to the patient's eye has been reduced by nearly 90% compared to traditional illumination, resulting in greater patient comfort during intense and prolonged observation. For more information, visit www.ibexeye.com.

RTVue Tracking Upgrade



Optovue Inc. released a real-time tracking upgrade for the RTVue Fourier-domain OCT (also called SD-OCT) system. Using a novel method of real-time video image processing, the software uses hardware already included with the RTVue system for following patient eye movement during the OCT scanning process. Optovue previously released a CAM (Cornea-Anterior Module) option that created the first OCT to offer scanning and analysis of both the posterior and anterior segments of the eye, and TCP (Total Cornea Power), which provided the cornea power in the central 3mm visual zone of post-refractive treated eyes. For more information, visit www.optovue.com.

iPad Apps

LUMA Vision Simulator

The new LUMA Vision Simulator eyecare app from Eyemaginations features on-screen drawing functionality and gives the user the ability to mark up images as well as view disease progressions and point-of-view scenes side-by-side on one screen. It allows doctors to explain the most common diseases of the eye. In addition, when used with Apple's Airplay, users of the new LUMA Vision Simulator are able to share the iPad screen images wirelessly to a television when used with AppleTV. All of the LUMA Eyecare Apps are available for download in iTunes. For more information, visit www.eyemaginations.com.

Marketing and Inventory Control

Gem-Where RFID Solution

Utilizing 900 MHz radio frequency identification (RFID) technology, Gem-Where is ultra-sensitive for dense tag environments around metal objects or in display cases. RFID Smart Tags are made of durable plastic and are reusable. The RG900 USB Reader links the Smart Tag to frames and de-links when the item is sold. The Radiant Wand captures your inventory by passing it over the wall and display showcases. Gem-Where can be used as "stand-alone" software for basic inventory reporting or for more detailed reports (inventory reconciliation and sales tracking) integrated into your point-of-sale software. For more information, visit www.ArchCrown.com. ■

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■ **30-31.** *25th Anniversary of the Cogan Ophthalmic History Society.* National Library of Medicine, Bethesda, Md. Contact George Bohigian, M.D., president, at bohigian@att.net or visit www.coganssociety.org for more information.

■ **30-April 1.** *Primary Eye Care Update.* Hill University Center, UAB Campus, Birmingham, Ala. Hosted by: University of Alabama at Birmingham School of Optometry. CE hours: 18. Call (205) 934-5701 or e-mail cbratton@uab.edu. For more information, visit www.uab.edu/optometry.

■ **31-April 1.** *6th Annual Conference on Comprehensive Eye Care.* Sheraton Hotel (formerly Crowne Plaza), Niagra Falls, N.Y. Hosted by: PSS EyeCare. CE hours: 16. Call (203) 415-3087 or e-mail education@psseyecare.com. For more information, visit www.psseyecare.com.

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■ **11-12.** *2012 WOA Spring Seminar.* Country Springs Hotel, Waukesha, Wis. Hosted by: The Wisconsin Optometric Association. Call (800) 678-5357 or visit www.woa-eyes.org.

■ **12-14.** *OptoWest 2012.* Renaissance Esmeralda Resort and Spa, Indian Wells, Calif. For more information, call (800) 877-5738 or e-mail events@coavision.org. Visit www.optowest.com.

■ **13-14.** *OAOP Annual Spring Congress.* Embassy Suites & Conference Center, Norman, Okla. Hosted by: the Oklahoma Association of Optometric Physicians. CE hours: 21. For more information, visit www.oaop.org.

■ **14-15.** *4th Annual Symposium on Ocular Disease.* Crowne Plaza Hotel, Tysons Corner, Va. Hosted by: PSS EyeCare. CE hours: 16. Call (203) 415-3087 or e-mail education@psseyecare.com. For more information, visit www.psseyecare.com.

■ **14-15.** *Miami Nice Symposium.* Colonnade Hotel, Coral Gables, Fla. Presented by: Miami-Dade Optometric Physician Association. CE hours: 17. For more information, contact Dr. Steve Morris at (305) 668-7700 or MPOPA.board@gmail.com. Visit www.MiamiEyes.org.

■ **18.** *North Jersey Optometric Seminar.* JCC MetroWest, West Orange, N.J. For more information, contact William B. Potter, O.D., at (609) 947-8545 or eyedoc21@aol.com.

■ **19.** *Central Jersey Optometric Seminar.* CentraState Medical Center, Freehold, N.J. For more information, contact William B. Potter, O.D., at (609) 947-8545 or eyedoc21@aol.com.

■ **20-21.** *Educational Meeting 2012.* Mission Inn, Howey-in-the-Hills, Fla. Hosted by: the Florida Chapter of the American Academy of Optometry. CE hours: 10. Contact Arthur T. Young, O.D., at eyeguy4123@msn.com or (239) 542-4627.

■ **20-22.** *WFOA 2012 Spring Seminar.* Sandestin Hilton Beach Resort, Destin, Fla. Hosted by: the West Florida Optometric Association. CE hours: 18. For more information, contact Tom Streeter at (850) 279-4361 or opttom@hotmail.com. Visit http://wfoameeting.com.

■ **20-24.** *ASCRS Symposium on Cataract, IOL, and Refractive Surgery.* McCormick Place West, Chicago. Hosted by: the American Society of Cataract and Refractive Surgery. For more information, call (800) 748-5064 or e-mail ascrs@xpressreg.net. Visit www.ascrsam.org.

■ **21-22.** *20th Annual Suncoast Educational Seminar.* Hyatt Regency Clearwater Beach Resort & Spa, Clearwater Beach, Fla. Hosted by: The Pinellas Optometric Association. For more information, contact Dr. Bruce Cochran at (727) 446-8186.

■ **25-29.** *10th Annual New Jersey Chapter—American Academy of Optometry.* Kingston Plantation, Myrtle Beach, S.C. CE hours: 16. For more information, contact Dennis H. Lyons, O.D., at (732) 920-0110 or dhl2020@aol.com.

May 2012

■ **2-5.** *MOA 2012 Annual Education Conference & Exposition.* Red Lion Colonial Hotel, Helena, Mont. Hosted by: The Montana Optometric Association. For more information, call (406) 443-1160 or visit www.mteyes.com.

■ **3-5.** *Mountain West Council of Optomestrists Annual Congress.* Caesar's Palace, Las Vegas. Hosted by: Mountain West Council of Optometrists. For more information, contact Tracy Abel, CMP, at (888) 376-6926 or tracyabel@earthlink.net. Visit www.mwco.org.

■ **6-10.** *ARVO 2012.* Greater Fort Lauderdale/Broward County Convention Center, Fort Lauderdale, Fla. Hosted by: The Association for Research in Vision and Ophthalmology. For more information, contact (240) 221-2900 or arvo@arvo.org. Visit www.arvo.org/am.

■ **18-20.** *Nova Southeastern University's 16th Annual Clinical Eye Care Conference & Alumni Reunion.* NSU College of Optometry. Contact Vanessa McDonald, M.S., Manager of Continuing Education, at (954) 262-4224 or oceaa@nova.edu. For more information, visit http://optometry.nova.edu/ce.

June 2012

■ **10-24.** *Majestic China 2012.* Hosted by: iTravelCE, LLC. CE hours: 20. Contact Dr. Bridgitte Shen Lee, at (832) 390-1393 or info@itravelce.com. For more info, visit www.itravelce.com.

■ **21-24.** *Maui 2012.* Wailea Beach Marriott Resort & Spa, Maui, Hawaii. Hosted by: *Review of Optometry.* Meeting chair: Paul Karpecki, O.D. CE hours: 14. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. For more information, visit www.revoptom.com/conferences.

July 2012

■ **2-6.** *CE in Belize.* Sunbreeze Hotel, Ambergris Caye, Belize. Hosted by: The International Academy of Optometry. For more information, contact Edward Paul, Jr., O.D., Ph.D., Education Director, at (910) 256-6364 or e-mail epauljr@aol.com. Visit www.CEinBelize.com.

■ **12-15.** *Colorado Vision Summit.* The Steamboat Grand, Steamboat Springs, Colo. Hosted by: Colorado Optometric Association. For more information, call (877) 691-2095 or e-mail CVSummit@visioncare.org. For more information, visit www.visioncare.org.

■ **19-22.** *Caribbean 2012.* Ritz Carlton, San Juan, Puerto Rico. Hosted by: *Review of Optometry*. Meeting chair: Paul Karpecki, O.D. CE hours: 14. Contact Lois DiDomenico at ReviewMeetings@Jobson.com or (866) 658-1772. For more information, visit www.revoptom.com/conferences.

■ **26-29.** *SECO Vancouver 2012.* The Westin Bayshore, Vancouver, British Columbia. CE hours: 14. E-mail seco@eventsthere.com or visit www.seco2012.com/vancouver.

August 2012

■ **3-5.** *Educational Retreat 2012.* South Seas Island Resort, Sanibel, Fla. Hosted by: Southwest Florida Optometric Association Inc. CE hours: 12. Contact Brad Middaugh, O.D., at (239) 481-7799 or swfoa@att.net. Visit www.swfoa.com.

■ **19.** *Orlando Super Sunday #1.* Orlando Campus, NOVA Southeastern University, Orlando, Fla. CE hours: 8. Contact Vanessa McDonald, M.S., at (954) 262-4224 or oceaa@nova.edu. Visit http://optometry.nova.edu/ce/supersunday.

September 2012

■ **5-8.** *International Vision Expo & Conference West 2012.* Sands Expo & Convention Center, Las Vegas. For more information, call (800) 811-7151 or e-mail inquiry@visionexpo.com. Visit www.visionexpowest.com.

■ **12-15**. *Envision Conference.* Hilton St. Louis at the Ballpark, St. Louis. For more information, call (316) 440-1530 or visit www.envisionconference.org.

■ **21-23.** *New Technology and Treatments in Vision Care.* California. Hosted by: *Review of Optometry*. Meeting chair: Paul Karpecki, O.D. CE hours: 15. For more information, contact Lois DiDomenico at ReviewMeetings@jobson.com or (866) 658-1772. Visit www.revoptom.com/conferences. ■

To list your meeting, contact:
Colleen Mullarkey, Senior Editor
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Diagnostic **Quiz**

A Consult from Neurology

By Andrew S. Gurwood, O.D.

History

A 36-year-old white female presented to the office for a consult following her admission to the hospital for drug-dependency.

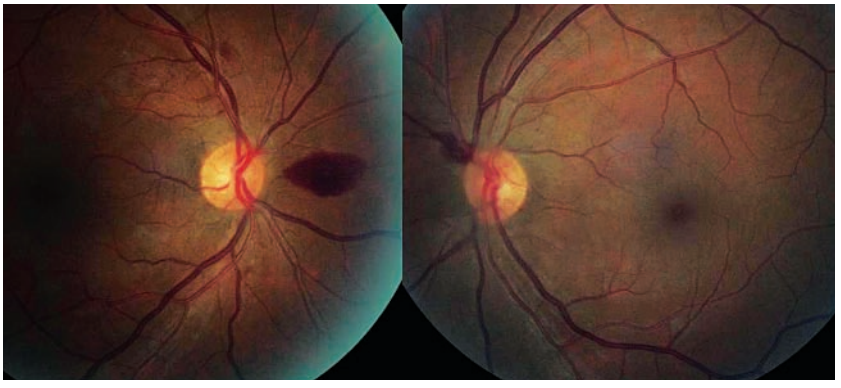
The neurology team had interpreted some brain abnormalities when reviewing her magnetic resonance imaging (MRI) scans and asked us to rule out the possibility of embolic disease.

Although the patient exhibited signs of confusion and mental abnormality, she had no visual complaints, history of ophthalmic disease, or evidence of ocular trauma or surgery.

Her systemic history was significant for substance abuse (both cocaine and heroin). She denied using any prescribed medications and reported no known allergies.

Diagnostic Data

Her entering visual acuity was 20/30 O.U. at distance and near, which was correctable to 20/20 O.U. with -1.00D sphere. Her pupils were equally round and reactive to light, with no afferent defect.



Fundus images of our 36-year-old patient who was referred by the neurology department (O.D. left, O.S. right). What do you notice?

Extraocular muscle movements were full O.U. Confrontation fields revealed a right homonymous inferior quadrantanopia that was consistent with her brain injury on MRI testing.

Slit lamp examination showed normal anterior segment structures and chambers. Her intraocular pressure measured 18mm Hg O.U. The significant fundus finding is illustrated in the photograph.

Your Diagnosis

How would you approach this case? Does this patient require any additional tests? What is your diagnosis? How would you manage this patient? What's the likely prognosis?

To find out, visit www.revoptom.com. Click on the cover icon for this month's issue, and then click "Diagnostic Quiz" under the table of contents. ■

Retina Quiz Answers *(from page 102):* 1) b; 2) a; 3) b; 4) a.

Next Month in the Mag

Our April issue features the 35th Annual Contact Lens Report, which will include:

- *Optometric Study Center: The Role of Inflammation in Contact Lens Wear* (earn 2 CE credits)
- *How to Minimize Multifocal Follow-Up*

Feedback

Review of Optometry welcomes questions and comments. E-mail Amy Hellem, editor-in-chief, ahellem@jobson.com, with "Letter to the Editor" as the subject line.

Or, write to *Review of Optometry*, 11 Campus Blvd., Suite 100, Newtown Square, PA 19073.

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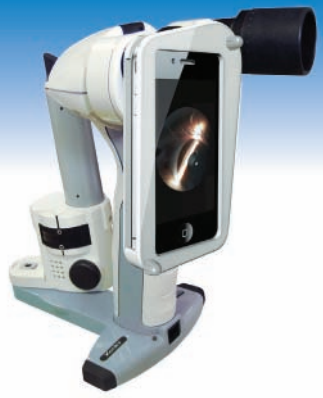

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References: 1. Dumbleton K, Woods C, Jones L, et al. Patient and practitioner compliance with silicone hydrogel and daily disposable lens replacement in the United States. Eye & Contact Lens. 2009;35(4):164-171. 2. Yeung K, Forister J, Forister E, et al. Compliance with soft contact lens replacement schedules and associated contact lens-related ocular complications: The UCLA Contact Lens Study. Optometry. 2010;81(11):598-607. 3. Jones L, Dumbleton K, Fonn D, et al. Comfort and compliance with frequent replacement soft contact lenses. Optom Vis Sci. 2002;79:259.

*Compliance with manufacturer-recommended replacement frequency.

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